Annexes

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Annexes 2.1 – HistologTM Scanner Instruction for use

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Histolog™ Scanner
Instructions for Use

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1. Table of Contents

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2. Explanation of symbols

LOT	Batch Code
REF	Catalog Number
SN	Serial Number
	Fragile, Handle with Care
IVD	In vitro diagnostic medical device
	Keep Dry
	Manufacturer
	Consult Instruction for Use
	Temperature limit
	Atmospheric Pressure Limitation
	Humidity Limitation
	Laser Class 1

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	Biohazard
	WEEE Directive
	Use Safety Gloves
	2 people required for lifting the device
CE	The device complies with European Directive 98/79/EC
	Manufacturing date
	This way up
	Non-ionizing radiation
	Equipotentiality. Present near the equipotential bonding socket.
	When followed by "**WARNING**" this symbol means "Warning! Failure to observe could result in injury or death." When followed by "**CAUTION**", this symbol means "Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the device." When found on equipment, this symbol means: "Attention: consult accompanying IFU". When found on labels, this symbol means: "Caution".
NOTE	A NOTE sign draws attention to useful information regarding a function or procedure.

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3. Introduction

This IFU describes the set-up, use and maintenance of the SamanTree Medical Histolog™ Scanner, and Histolog™ Software version 1.1 and above, until further notice.

It is intended for use by individuals trained in the healthcare and biomedical professions

⚠**WARNING** This IFU contains important information for the safe use of this product. Please read the entire IFU, including **WARNINGS** and **CAUTIONS** (Section 4 of this IFU), before using this product. Failure to properly follow Warnings, Cautions and Instructions could result in death or serious injury to the patient or operator.

3.1. Manufacturer

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1004 Lausanne
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3.2. Device description

The Histolog™ Scanner is a digital microscopy scanner that acquires and displays microscopic histology images of the superficial layers of fresh thick tissue. To acquire images the fresh tissue is prepared and loaded in the device as explained in section 6.2 of this IFU.

The Histolog™ Scanner allows for acquisition of two types of images over extra-large areas of tissue surface (several cm^2). The first type of images is rapid "Preview" images that are used to verify position of the fresh tissue on the scanner interface. It takes about 10 seconds to produce a Preview image. The second type of images are high resolution "Acquire" images of higher resolution that show sub-cellular details such as nucleus on a fresh tissue. It takes less than 5 minutes to produce an Acquire image. "Preview" and "Acquire" images are launched according to instructions from section 6.4 of this IFU.

With the Histolog™ Scanner, the excised fresh tissue can be immediately analyzed without the need for freezing or fixing, potentially assisting the healthcare professional in forming a clinical judgement during cancer intervention.

The tissue is imaged using fluorescent contrast agent following a technique similar to a fluorescence confocal microscope to allow an observation of the tissue from a morphologic level up to a sub-cellular magnification required for histo-pathological analysis of the tissue. The Histolog™ Scanner is for in vitro diagnostic use.

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3.3. Intended Use

The Histolog™ Scanner is intended to be used as a tool for acquisition, display, storage and retrieval of images of excised surgical tissue for review by physicians, to assist in forming a clinical judgment.

3.3.1. Indication For Use

Histolog™ Scanner's purpose is to help physicians to visualize margins of excised tissue specimen (ex-vivo) during cancer surgery. Histolog™ Scanner can be used with any type of tissue, in order to provide data to allow healthcare specialists to form a clinical judgment when assessing resection margins. Identified published data support in particular such indication for skin cancer as well as for breast cancer examination. The Histolog™ Scanner can only be used by trained healthcare professionals.

3.3.2. Contraindications

The Histolog™ Scanner is not indicated in the following cases:

- In-vivo tissue examination
- Use in domestic environment

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4. Warnings & Precautions

4.1. Safety Instructions

Use the equipment only for the purpose described in the instructions for use. Do not use the equipment if it is not working properly, or if it has suffered any damage. Misuse can cause electrocution, burns, fire and other hazards.

All the components of the system located in the inner cavity of the system are not intended to be manipulated by the user. The interior of the Histolog™ Scanner may be serviced only by SamanTree Medical authorized technical personnel.

When using staining agents, conform to the products safety instructions of the agent.

4.2. Warnings

⚠ **WARNING** Do not operate the Histolog™ Scanner in case of damage to the optical chip [M1].

⚠ **WARNING** The Histolog™ Scanner is not a sterile device. For use in intraoperative setting, the Histolog™ Scanner shall be located outside the sterile surgical area.

⚠ **WARNING** Always wear gloves when handling human tissue, or when required by the safety instructions of the staining agent used.

⚠ **WARNING** Avoid touching the device with gloves stained by tissue specimen or related fluids to prevent contamination.

⚠ **WARNING** This equipment is not compatible with magnetic resonance (MR) or explosive environments.

⚠ **WARNING** Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching it.

⚠ **WARNING** The Histolog™ Scanner is considered a heavy object. Lifting and carrying must be carried out by two persons using the wheel support frame.

⚠ **WARNING** Handles are not provided for lifting the device, but exclusively have a function for pushing/pulling.

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⚠ **WARNING** Do not connect the power cable plug into a difficult to access socket. In case of emergency the plug must be accessible.

⚠ **WARNING** The interior of the Histolog™ Scanner may be serviced only by SamanTree Medical authorized technical personnel. Unauthorized access could result in injury or death.

4.3. Cautions

⚠ **CAUTION** When parking or stopping the device, all wheel brakes must be pressed down in locking position. Accordingly, all wheel brakes must be released before moving/transporting the device.

⚠ **CAUTION** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional radio frequency (RF) sources), as these can interfere with proper operation.

⚠ **CAUTION** Do not use this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.). It may cause damaging electrostatic discharges that may cause erroneous results.

⚠ **CAUTION** Wait 5 minutes before switching on the device after a switch off.

⚠ **CAUTION** The Optical Chip [M1, see section 5.2 of this IFU] is a fragile and vulnerable component and must be protected against dust, spills and any contact in order to preserve imaging performance. Keep protective cap [M2, see section 5.2 of this IFU] in position at all time, except when inserting or removing the disposable tissue specimen dish. In case the Optical Chip is visibly damaged or stained, stop using the device and contact SamanTree Medical authorised technical personnel.

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4.4. Laser safety

LASER 1

CLASS 1 LASER PRODUCT

The Histolog™ Scanner is a Class 1 laser product, as per IEC 60825-1:2014-05.

Laser radiation in the visible wavelength range is emitted from the optical chip located under the optical interface of the specimen imaging area during image acquisition (for both preview and image acquisition modes).

Laser wavelength:	488 ± 5 nm
Max output power:	10 mW (maximum emission from extended source)

The Histolog™ Scanner embeds a Class IIIB laser component with the following characteristics:

Wavelength:	488 ± 5 nm
Max output power:	200 mW
Beam divergence:	< 0.7 mrad

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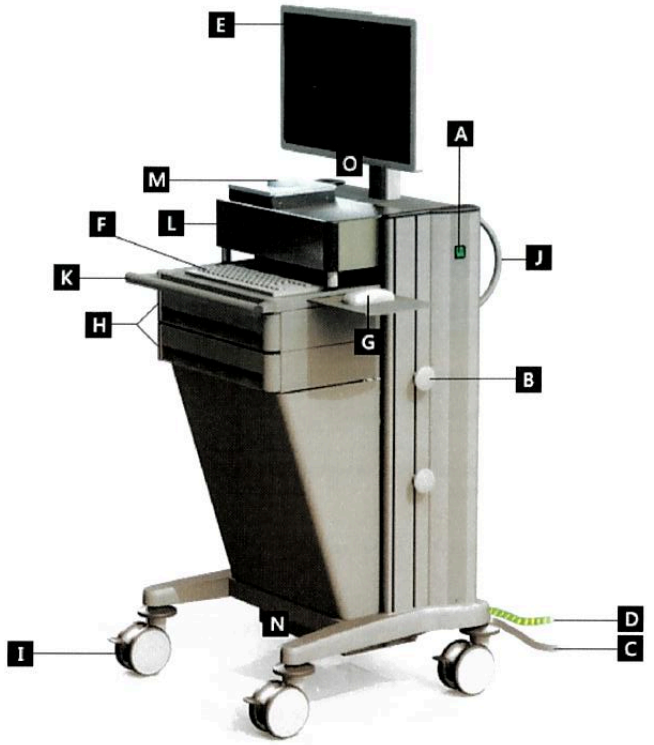
5. System Overview

5.1. Overview



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The Histolog™ Scanner consists of the following components:

A. ON/OFF Power Switch
B. Cable Winder
C. Power Cable
D. Equipotential Bonding Cable
E. Display Monitor
F. Keyboard
G. Mouse
H. Drawers (2X)
I. Swivel caster wheels with brakes (4X)
J. Backside Handles (2X)
K. Frontside Handle
L. Microscopy Instrument
M. Specimen Imaging Area
N. Insulating transformer
O. USB port
P. Histolog™ Scanner Software with its graphical user interface (GUI) (not shown)

5.2. Component Description

The ON/OFF power switch [A] is of green color and located near the top of the right vertical rail of the Histolog™ Scanner device. The Histolog™ Scanner components are powered through a medical-grade isolation transformer [N].

A cable winder [B] located on the side of the Histolog™ Scanner allows to roll-up excess length of the power cable [C] and the equipotential bonding cable [D], and secure these cables to the device during transportation.

The display monitor [E] serves to display the graphic user interface and the images of the specimen. The monitor presents a protective front glass panel allowing full standard cleaning and disinfecting procedure to prevent contamination (see section 9.2.2 of this IFU). A downstream USB port [O] is located under the display monitor and can be used to connect an external USB data storage device for exporting Histolog™ Scanner images.

The keyboard [F] and the mouse [G] are the standard text and pointing input devices intended for user to operate the Histolog™ Scanner and navigate in the digital images displayed by the monitor.

The Histolog™ Scanner is equipped with 2 drawers [H] for storage of device documentation and related small materials.

The Histolog™ Scanner is equipped with four swivel caster wheels with brakes [I]. When parking or stopping the device, all wheel brakes must be pressed down in locking position. Accordingly, all wheel brakes must be released before moving/transporting the device.

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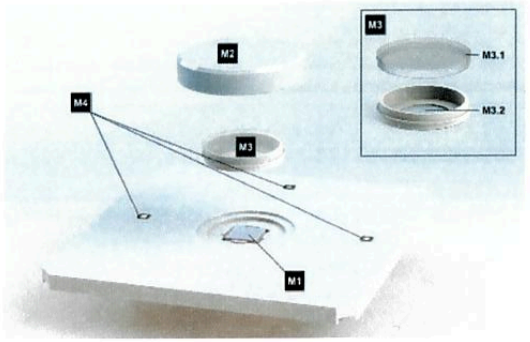
Two backside handles [J] and one frontside handle [K] allow pulling/pushing the device, when wheel brakes are released.

⚠ **CAUTION** Handles are not intended for lifting the device, but exclusively have a function for pushing/pulling.

The microscopy instrument [L] is the main functional component of the system. It contains the optical system that scans the surface of the specimen.

The Specimen Imaging Area [M] is the location on the microscopy instrument [L] where tissue specimen is placed and where the imaging occurs.



The Specimen Imaging Area contains the following components:

M1. Optical Chip
M2. Protective Cap
M3. Histolog™ Dish
M4. Specimen Orientation Marks

The Optical Chip [M1] is the core imaging component of the Histolog™ Scanner.

⚠ **CAUTION** The Optical Chip [M1] is a fragile and vulnerable component and must be protected against dust, spills and any contact in order to preserve imaging performance

⚠ **CAUTION** In case the Optical Chip is visibly damaged or stained, stop using the device and contact SamanTree Medical authorized technical personnel.

A Protective Cap [M2] protects the optical chip from dust, spills and any type contact.

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⚠**CAUTION** For protection of the optical chip, keep the blank protective dish and the protective cap [M2] in position at all time, except when inserting or removing the disposable Histolog™ Dish. Do not throw this protective dish away.

The Histolog™ Dish [M3] is the container in which the tissue specimen is placed for imaging. The Histolog™ Dish has a closable lid [M3.1]. The bottom of the dish is made from an optical interface [M3.2] that allows imaging by the optical chip.

The specimen imaging area features physical geometric orientation marks [M4]. Corresponding digital marks can be overlaid to the digital image displayed by the Histolog™ Scanner graphical user interface to provide information on the tissue orientation (see section 6.4.6 of this IFU).

The Histolog™ Software [P] is the software application supplied by SamanTree Medical SA for the operation of the Histolog™ Scanner. It has a graphical user interface (GUI) through which the user can interact with the device.

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6. Use of the Histolog™ Scanner

6.1. Getting Started

⚠**CAUTION:** The device must be delivered, installed, assembled, disassembled, and retired by SamanTree Medical SA authorized technical personnel only.

6.1.1. Preliminary steps

1. Using the handles, move the Histolog™ Scanner to desired location with level ground.
2. When in place, lock the wheel brakes to prevent unintended movement of the Histolog™ Scanner.
3. Connect the equipotential bonding cable to the room's equipotential bonding studs, if available.
4. Connect the power cable to the local electrical mains power outlet.

⚠**WARNING** The protective earthing connection of the Histolog™ Scanner is performed through the power cable connection. If this cable is damaged, the device must not be connected to the mains power.

6.1.2. Switching ON

1. Turn ON main power switch [A]. Computer boots up and Histolog™ Software launches automatically.

⚠**CAUTION** After switching ON the Histolog™ Scanner, it is recommended to wait 5 minutes before starting acquiring images to allow system warm up.

6.1.3. Switching OFF

1. Quit Histolog™ Scanner graphical user interface by selecting *Application* menu and then, *Quit*.

2. Shutdown computer by selecting '*Shutdown*' option from the *Start Menu* opened by clicking on the bottom left button of the computer desktop.
3. Once computer has shut down and 'No Signal' is seen on the monitor, turn OFF main power switch [A].

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6.2. Tissue Specimen Imaging

WARNING: Always wear gloves for tissue manipulation, staining and positioning on the optical interface.

CAUTION: Make sure to follow your healthcare facility's procedure / guidelines to ensure proper tissue orientation tracking or agree on the tissue orientation tracking method before starting the surgery.

6.2.1. Recommended tissue specimen staining procedure

WARNING: When using proflavine, or any other staining agent, the user must comply with the products safety instructions provided by the manufacturer of the staining agent.

NOTE Size of the specimen should not exceed the size of the Histolog™ Dish to prevent leakages of biological fluids.

NOTE Before performing a measurement on the tissue specimen, make sure the specimen is wiped free of excess fluid by swabbing it gently with a clean cloth or tissue.

NOTE Excess of blood on the optical interface [M3.2] will negatively impact image quality.

NOTE Histological inks shall not be applied on the tissue specimen prior imaging with the Histolog™ Scanner.

1. Swab the fresh tissue specimen briefly to remove excess of blood with paper towel or compress.
2. Dip the tissue specimen into the Proflavine solution for 30 sec.
3. Rinse by dipping it few seconds in phosphate buffered saline solution.

In order to maximize the microscopic visualization of the tissue specimen by the Histolog™ Scanner, tissue specimen has to be stained with a contrasting agent before its deposit in the Histolog™ Dish [M3]. The recommended agent compatible with the Histolog™ Scanner is the Proflavine (CAS 92-62-6). Proflavine is not part of the Histolog™ Scanner device and is available off the shelf. SamanTree Medical recommends to use the Proflavine at 0.01% concentration diluted in phosphate buffered saline solution.

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6.2.2. Tissue specimen positioning

NOTE Do not use an expired Histolog™ Dish.

NOTE A new Histolog™ Dish [M3] shall be used every time a new tissue specimen is imaged and as soon as dried residual tissue specimen material is noticed on the optical interface (see section 9 of this IFU).

NOTE Make sure that all the tissue surface of interest is in contact with the optical interface [M3.2] to guarantee the complete imaging of the specimen.

NOTE After removing the new Histolog™ Dish from its protective packaging, place it on a dry, clean and flat surface to avoid any damage to the optical interface [M3.2].

1. Open the closable lid [M3.1] of the Histolog™ Dish.
2. Place and center the tissue specimen in the Histolog™ Dish [M3], face of interest pointing downwards.
3. Make sure the tissue specimen is centered on the optical interface [M3.2]

Put back the lid [M3.1] to close the Histolog™ Dish.

6.2.3. Inserting the Histolog™ Dish in the Histolog™ Scanner

WARNING Always wear gloves when manipulating the Histolog™ Dish, even if its lid is closed.

CAUTION Leakage of fluids or contact with the optical chip may irremediably damage the Histolog™ Scanner. If leakage of fluid occurs inside the device or if optical chip is damaged, do not use the Histolog™ Scanner. Contact SamanTree Medical authorized technical support for assistance.

Once the tissue specimen is ready to be imaged, insert the Histolog™ Dish in the Histolog™ Scanner as follows:

1. Remove protective cap [M2]

   NOTE Removing the protective cap exposes the optical chip to environmental hazards. Special care should be taken to avoid any contact with the optical chip and to prevent dusts or spills from reaching the optical chip.

2. Remove blank protective dish

   NOTE Place the blank protective dish on a dry, clean and flat surface to avoid any damage to its optical interface [M3.2].

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3. Gently insert Histolog™ Dish containing the tissue specimen to be imaged in its dedicated location.

   Orientate the Histolog™ Dish by paying attention to geometric orientation marks [M4]. These markers can be displayed in the preview and images accordingly to their physical position on the device to illustrate tissue specimen orientation in the images (see section 6.4.6 of this IFU).

   NOTE Ensure that the Histolog™ Dish lid is closed before inserting it in Histolog™ Scanner.

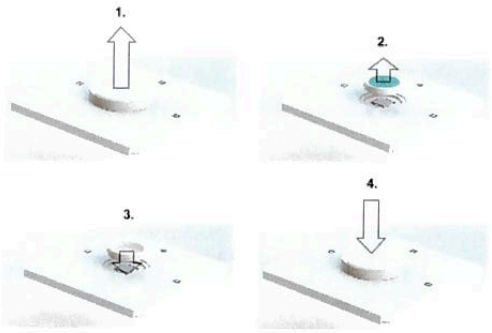
   NOTE Ensure that the outer surfaces of the Histolog™ Dish are clean before inserting it in Histolog™ Scanner.

   ⚠ **CAUTION** Never apply pressure on the Histolog™ Dish. Pressuring on the Histolog™ Dish may damage its optical interface and cause leakage inside the Histolog™ Scanner.

4. Replace protective cap

   NOTE Quickly replace the protective cap to protect the optical chip from dusts or accidental spills.

5. The tissue specimen is properly positioned for imaging. Follow section 6.4 of this IFU for imaging.



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6.2.4. Removing Histolog™ Dish from the Histolog™ Scanner

⚠ **WARNING** Always wear gloves when manipulating the Histolog™ Dish, even if its lid is closed.

⚠ **CAUTION** Leakage of fluids or contact with the optical chip may irremediably damage the Histolog™ Scanner. If leakage of fluid occurs inside the device or if optical chip is damaged, do not use the Histolog™ Scanner. Contact SamanTree Medical authorized technical support for assistance.

After tissue specimen has been imaged, remove the Histolog™ Dish as follows:

1. Remove protective cap [M2]

   NOTE Removing the protective cap exposes the optical chip to environmental hazards. Special care should be taken to avoid any contact with the optical chip and to prevent dusts or spills from reaching the optical chip.

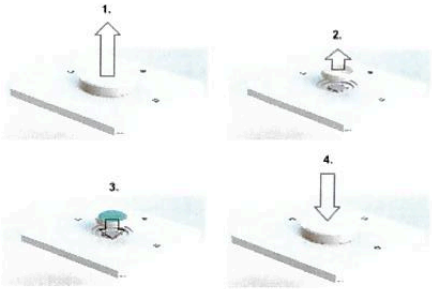
2. Gently remove the Histolog™ Dish

   ⚠ **CAUTION** Never apply pressure on the Histolog™ Dish. Pressuring on the Histolog™ Dish may damage its optical interface and cause leakage inside the Histolog™ Scanner.

3. Replace the blank protective dish
   NOTE Ensure that the outer surfaces of the blank protective dish are clean before inserting it in Histolog™ Scanner.

4. Replace protective cap

   NOTE Quickly replace the protective cap to protect the optical chip from dusts or accidental spills.



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6.3. Histolog™ Software graphical user interface

Use Histolog™ Software graphical user interface (GUI) to control operations of the Histolog™ Scanner and to work with digital images produced by the device. The GUI is composed of a main control interface window and image windows that are visible only when images are opened.

6.3.1. Main control interface window

The main control interface window shown on the figure above provides allows users to control all operations of the device.

The controlled operations are:

I. Working with production of a Preview image of a tissue specimen:
   A. Launching a Preview image production - controlled with button marked as (1) on the figure;
   B. Observing progress of a Preview image production - controlled with the progress indicators (4);
   C. Cancelling a Preview image production - controlled with button (3).

II. Working with production of an Acquisition image of a tissue specimen:
   A. Launching an Acquisition image production - controlled with button (2);
   B. Observing progress of an Acquisition image production - controlled with the progress indicators (4);
   C. Cancelling an Acquisition image production - controlled with button (3).

III. Working with produced images:
   A. Showing and hiding a scale on produced images - controlled with buttons (5) and (7);
   B. Showing and hiding orientation marks on produced images - controlled with buttons (6) and (7);
   C. Painting and unpainting images with histological colormap - controlled with buttons (8);
   D. Navigating through the two-dimensional space of an image - the mouse/mousepad drag control is activated with button (9) and used on images windows to navigate;
   E. Measuring distances on images - the mouse/mousepad line control is activated with "Line" button (10) and used on images windows to draw lines, distances that correspond to the lines drawn on images are measured with "Measure" button (10);
   F. Producing and saving views on images - image views are produced from images windows through zooming in/out, navigating to the area of interest, setting scale and/or orientation marks, painting/unpainting the histological colormap; the views are saved with "Save View" button (11).
   G. Using Notes tool to produce, save and review notes on the produced images and views - Notes for a given image appear in the GUI area (12) whenever an image is under focus of mouse/mousepad control; users can review and edit notes of previously produced images using the keyboard;
   H. Using Gallery tool for browsing through the collection of produced images - button (13) and for re-opening previously produced images and views - controlled with button (14); the Gallery's directory and file structure appears in the GUI area (12) and allows to browse through and open for viewing in images windows the previously produced images and views.
   I. Using Gallery content selection checkboxes located next to the corresponding content items in the Gallery browsing GUI area (12). Copying selected items to an external USB drive is controlled with "Export Selection" button (15).

Permanent deletion of selected Gallery items is controller with "Delete Selection" button (16).
   J. Copying the full gallery content to an external USB drive - controlled by using the menu "Images" (18) through the option "Copy to USB".

IV. Using Histolog™ Scanner service functionalities:
   A. Testing the current state of the device - controlled by using the menu "Application" (17) through the option "Self-test".
   B. Quitting Histolog™ Software - controlled by using the menu "Application" (17) through the option "Quit".

6.3.2. Image windows

Image windows provide means for users to view images and to navigate through the two-dimensional space of an image using:

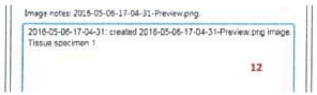
- zoom in/out ("+" and "-" keyboard keys)
- drag to move using mouse/mousepad (through the drag control (9)).

6.4. Examples of use of Histolog™ Software graphical user interface

6.4.1. Produce and view a Preview image of a tissue specimen

To produce a Preview image of a tissue specimen:

1. Click on "Preview" button (1);
2. Wait for both of the progress indicator controls (4) to indicate 100% completeness state.
   a. You may cancel the current operation at any time before its full completeness using "Cancel" button (3).
3. The Preview image will be opened in its dedicated image viewer window; its Notes file will be displayed in the corresponding GUI area (12). You may edit the contents of Notes as needed.



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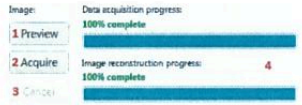
6.4.2. Produce and view an Acquire image of a tissue specimen

To produce an Acquire image of a tissue specimen:



1. Click on "Acquire" button (2);
2. Wait for both of the progress indicator controls (4) to indicate 100% completeness state.
    a. You may cancel the current operation at any time before its full completeness using "Cancel" button (3).
3. The Acquire image will be opened in its dedicated image viewer window; its Notes file will be displayed in the corresponding GUI area (12). You may edit the contents of Notes as needed.

6.4.3. Open an image from the Gallery

To open an image from the Gallery:

1. Click on "Gallery" button (13) to activate Gallery explorer (12).
2. Browse in Gallery explorer to locate an image that you want to open.
3. Click once on the located image to open it in the viewer.

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6.4.4. Use navigation in a displayed image

Images are displayed on your screen in the image viewer windows. For a displayed image use zoom in and zoom out functions (activated with "+" and "-" keyboard keys) and drag to move mouse/mousepad navigation (either holding "Spacebar" keyboard key or through the drag control (9)) on the image viewer window to locate and magnify an area of your interest on the image.

6.4.5. Close a displayed image

To close an image displayed on the screen click on the red cross icon that is located in the top right corner of the image viewer window.

6.4.6. Show Scale and Orientation Marks on a displayed image

When a Preview or an Acquired image is displayed:

1. Use "Scale" button (5) to show the scale of your current view.
2. You can remove the display of the scale using the "Hide" button (7).
3. Use "Orientation marks" (6) button to show the marks in the current view.
4. You can remove the display of the orientation marks using the "Hide" button (7).

NOTE The only way to keep these insertions for future use after closing the image is to save the view with insertions using the 'Save View' functionality described below.

6.4.7. Save a view of an Acquire image of a tissue specimen

NOTE This functionality can also be used on a Preview image.

You can save a view of a displayed Acquire image of a tissue specimen. To save a view do the following:

1. Using mouse/mousepad select the opened Acquire image window under focus.
2. Locate and magnify an area of your interest on the image as described in "Use navigation in a displayed image" above.
3. Optionally display scale and/or orientation marks as described in "Show Scale and Orientation Marks on a displayed image" above.
4. Use "Save view" button (11) to save your current view as a separate image in the Gallery.
5. Select your preferred file name for the view and click OK in the displayed "Save View Dialog" window.

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6.4.8. Use notes for an image of a tissue specimen

You can keep notes for an image of a tissue specimen. Notes are kept in special notes files associated with images. Any original Preview or Acquire image has its corresponding notes file that you can edit whenever the corresponding image is opened in the viewer and the viewer window is under focus.

Also, you can use notes for views that are saved from original images. All the views derived from an original image share the same notes file that is their original image notes file.

To use notes for an image of a tissue specimen do the following:

1. Using mouse/mousepad click on the opened image window to select it under focus.
2. Click on the "Notes" area (12) and change the text of the notes file associated with the image, e.g. add some text describing the case that this image represents.

Your notes are saved automatically. You can close the image window or select another image window under focus, your notes will be available for future use whenever their corresponding image will be opened in the viewer and the viewer window will be under focus.

NOTE Images and image notes stored on the device are not encrypted. Do not enter nor store sensitive information on the device.

6.4.9. Export full Gallery content to external storage

To export images produced with Histolog™ Scanner to an external storage:

1. Ensure that your external USB storage device has enough available space to store the contents of Histolog™ Scanner images Gallery. The device will inform you through a GUI message on impossibility to export images in the case if there will be a lack of available space.
2. Connect your external storage device to USB port [O] of Histolog™ Scanner.
3. Use "Copy to USB" option of the menu "Images" (18) to copy the images of the Gallery to your storage device.
4. Wait for the copying progress to reach 100% level and for the copying success confirmation message to appear on the screen. Press OK to dismiss the message.
5. Disconnect your storage device from Histolog™ Scanner USB port.

6.4.10. Export selection of Gallery content to external storage

To export a selection of images produced with Histolog™ Scanner to an external storage:

1. Press "Gallery" button (13) and browse Gallery in GUI area (12) to locate the content that you want to export.

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2. Select Gallery content that you want to export using selection checkboxes located next to the content items in the Gallery browsing GUI area (12).
3. Ensure that your external USB storage device has enough available space to store the selected contents of Histolog™ Scanner images Gallery. The device will inform you through a GUI message on impossibility to export your selection in the case if there will be a lack of available space.
4. Connect your external storage device to USB port [O] of Histolog™ Scanner.
5. Use "Export Selection" button (15) to copy the selected content of the Gallery to your storage device.
6. Wait for the copying progress to reach 100% level and for the copying success confirmation message to appear on the screen. Press OK to dismiss the message.
7. Disconnect your storage device from Histolog™ Scanner USB port.

6.4.11. Permanently delete images from the system

1. Press "Gallery" button (13) and browse Gallery in GUI area (12) to locate the content that you want to delete.
2. Select Gallery content that you want to delete using selection checkboxes located next to the content items in the Gallery browsing GUI area (12).
3. Use "Delete Selection" button (15) to permanently delete the selected Gallery content. If you are sure that you really want to permanently delete the selected content, then confirm your action on the emerging GUI confirmation window.

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7. Storage

1. Turn OFF device by following section 6.1.3 of this IFU
2. Unplug the power cable
3. Unplug the equipotential bonding cable
4. Place the power cable and the equipotential bonding cable on the cable winder
5. Make sure that the blank protective dish and the protective cap [M2] are properly mounted
6. Clean and move the device to the storage space

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8. Transport

Before moving the Histolog™ Scanner, please ensure that:

1. The power and the equipotential cables are disconnected from mains outlet and secured on the cable winder
2. The brakes of the caster wheels are released

The equipment should only be moved at a maximum walking pace of 6 km/h.

⚠ **WARNING** The Histolog™ Scanner is considered a heavy device.

Lifting and carrying must be carried out by two persons using the extensions of the base.

⚠ **WARNING** Handles are not provided for lifting the device, but exclusively for pushing/pulling.

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9. Maintenance & Cleaning

9.1. Maintenance

The Histolog™ Scanner device is subject to an annual maintenance by SamanTree Medical SA authorised technical personnel.

9.1.1. Removing/Replacing the Histolog™ Dish

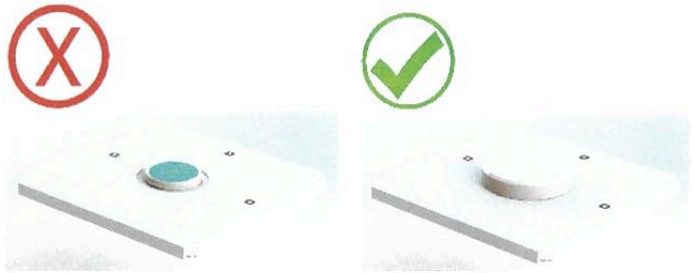
See section 6.2.3 and 6.2.4 of this IFU.

9.2. Cleaning procedures

9.2.1. Cleaning the Histolog™ Scanner

⚠ **WARNING** System cleaning should be performed only when the system is shut down and disconnected from the main power source. Cleaning with the system turned on may be hazardous to the operator and/or destructive to the system.

NOTE Ensure that the protective cap [M2] is in position before proceeding with the cleaning of the specimen imaging area [M].



⚠ **WARNING** NEVER clean the optical chip [M1] nor the circular area around it where the Histolog™ Dish is inserted.

NOTE The system shall be cleaned only using wipes lightly moistened with a recognized cleaning product for medical equipment. Read and follow all label instructions on the cleaning product (see examples of standard products below).

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SamanTree Medical recommends the following standard cleaning disinfectants:

Product	Manufacturer
Incidin PLUS 0.5%	Ecolab
Septiwipes	Dr. Schumacher
Steriwipes C	Cleanplanet

- Before the Histolog™ Scanner can be placed in the operating room area, the device shall be cleaned and disinfected according to internal procedures of the hospital.
- During an intra-operative use of the device, any drops of biological fluids found on the Histolog™ Scanner outside the Histolog™ Dish shall be cleaned immediately with wipes lightly moistened with a recognized cleaning product for medical equipment according to internal procedures of the hospital.
- After every use and before the storage, the Histolog™ Scanner shall be cleaned and disinfected according to internal procedures of the hospital.

9.2.2. Cleaning the display monitor

The display monitor presents a protective front glass panel and allows full cleaning and disinfecting to prevent contamination.

The display monitor shall be cleaned only using wipes lightly moistened with a recognized cleaning product for medical equipment. Read and follow all label instructions on the cleaning product.

⚠ **CAUTION** Avoid the use of the following products: strong alkalis lye, strong solvents, acids, detergents with fluoride, detergents with ammonia, detergents with abrasives, steel wool, sponge with abrasives, steel blades, cloth with steel thread.

NOTE Take care not to damage or scratch the front glass. Be careful with rings or other jewelry and do not apply excessive pressure on the front glass.

9.2.3. Cleaning the keyboard

1. Lock keys by pressing the left & right Control ("Ctrl") keys together for 3 seconds, or by using the lock key on the keyboard.
2. Clean the surface by wiping, brushing or spraying it using only cloths, sponges or soft bristle brushes .
3. Wipe dry with cloth or allow to air dry.
4. After cleaning, unlock keys by pressing the left & right Control ("Ctrl") keys together for 3 seconds, or by using the lock key on the keyboard.

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9.2.4. Cleaning the mouse

1. Clean the surface by wiping, brushing or spraying it using only cloths, sponges or soft bristle brushes.
2. Wipe dry with cloth or allow to air dry.

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10. Disposal

10.1. Histolog™ Dish

Dispose of the Histolog™ Dish according to local procedure for contaminated material.

10.2. Histolog™ Scanner

The Histolog™ Scanner shall be discarded according to local regulations for medical equipment disposal.

Follow the Separate Collection for Electrical and Electronic Equipment in compliance with Waste Electrical and Electronic Equipment Directive WEEE.

All electrical and electronic equipment provided with system released after 13 August 2005 is marked with a separated collection for Electrical and Electronic Equipment symbol, indicating that this equipment must undergo separate collection for disposal, in countries where EU directive 2002/96/EC is in effect.

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11. Limited Warranty

The Histolog™ Scanner and products are sold pursuant to the Histolog™ Scanner Sales Agreement previously entered into between the Company and Customer and are warranted by the manufacturer to be free from defective material or poor workmanship. Liability under this warranty is limited to the Company's obligation to repair or to replace at no cost to the customer, any product(s) found to be defective under normal use and while servicing throughout the Warranty Period.

Included in this limited warranty are:

- All labor costs
- All shipping costs
- Any associated expenses to repair and maintain the Histolog™ Scanner.

SamanTree Medical may, at their discretion, provide a refurbished replacement device on a temporary basis while the Histolog™ Scanner is being repaired. Although refurbished to functional factory standards, the temporary replacement device may not be equivalent in appearance to the units returned to the Company for repair or service.

Every effort will be made to have all repairs completed in shortest possible time frame.

A Company service engineer or other authorized representative will perform all repairs.

The Company determines all field installable software and hardware upgrades.

This limited warranty is contingent upon the following:

- The User is required to reasonably troubleshoot with SamanTree Medical technical support personnel to verify the nature of the problem before returning any item or device for repair. Information regarding the specific nature of the failure and detailed description of logged messages is required. All returns MUST BE authorized by SamanTree Medical.
- SamanTree Medical's subsequent examination of returned items satisfactorily confirms that the defect was not caused by improper use or abuse of the Histolog™ Scanner.
- The Histolog™ Scanner was not repaired or altered by persons other than SamanTree Medical personnel or its authorized representatives.
- Cables and accessories are specifically excluded from this limited warranty.

The temporary replacement device is shipped for return to SamanTree Medical within 3 days of the time that the repaired Histolog™ Scanner is received. If the temporary replacement device is not shipped within this set 3 days period, SamanTree Medical will bill the user at the list price for a replacement unit. The shipment back to SamanTree Medical may be

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conveniently arranged with the company representative. SamanTree Medical may also pick-up its temporary equipment.

Opening the Histolog™ Scanner or breaking the internal warranty seals will void this limited warranty

In the event SamanTree Medical determines that the customer is entitled to receive a temporary refurbished device pending repair of the customer's Histolog™ Scanner, SamanTree Medical will make every effort to ship the temporary replacement unit within 1 week of the decision, provided that such a device is available in stock.

Any external customer identification, labels, stickers etc. sent with the Histolog™ Scanner by the Customer to SamanTree Medical for repair will not be returned to the customer.

SAMANTREE MEDICAL DISCLAIMS **ALL** OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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12. Troubleshooting

12.1. Troubleshooting

Issue	Action to take
Device does not power up	Check the power supply connection and verify that Histolog™ Scanner is switched ON (power switch in "I" position).
Nothing is displayed on the screen	Verify that monitor's power indicator light is illuminated. If not, switch ON monitor's power button, located on the side of the monitor's power indicator.
Device cannot be moved	Verify that wheel brakes are released (in upward position).
Acquisition stops before reaching 100%	Cancel and relaunch Acquisition. If issue persists, the disk space may be full. Cancel the acquisition, delete images from the Gallery, then relaunch the acquisition.
GUI is not responsive	Restart operating system (Start menu, Restart)
Device cannot acquire images	Turn OFF the device, wait 5 minutes, and turn it back ON (as per Getting Started instructions).
Poor quality of images	Make sure the tissue specimen is wiped free of excess fluid by swabbing it gently. Disposable Histolog™ Dish is dirty, please use a new dish to image your tissue specimen. Make sure that all the tissue surface of interest is in contact with the optical interface of disposable Histolog™ Dish. Apply to the tissue specimen a second tissue staining procedure.

If the problem cannot be corrected, perform the following steps:

1. If possible, quit Histolog™ Software graphical user interface by selecting *File*, *Close* and shutdown the computer by selecting the *Shutdown* option in the *Start Menu*.
2. Once computer has shut down and no display is shown on the monitor, turn OFF main power switch on the vertical rail of Histolog™ Scanner device.
3. Remove the power plug from the wall outlet.

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4. Remove the Histolog™ Scanner from service and contact SamanTree Medical for technical support (contact information may be found in section 3.1).

13. Product Catalog Codes

For purchasing replacement parts from SamanTree Medical or from an authorized SamanTree Medical distributor, please use the following product catalog numbers.

Product Catalog #	Description
HL.SR110	Histolog™ Scanner
HL.DH120-01	Histolog™ Dish
HL.DH120-30	Histolog™ Dish, pack of 30 units
HL.DC140-EU	Histolog™ Scanner IFU

NOTE Always use parts supplied by SamanTree Medical SA or other authorized representative.

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14. Device specifications/Technical Information

14.1. Technical Specifications

Dimensions (W x D x H)	0.70 x 0.66 x 1.67 m
Weight	120 kg
Ingress Protection Level	IP68 (keyboard) IP68 (mouse)
Electrical Power Input	100-240 VAC, 50/60 Hz
Rated Power	275 W
Power Cable Length	5 m
Equipotential Bonding Cable Length	5 m
RoHS Compliant	Yes
USB port standard	2.0
Fuse type	T 6.3AL 250VAC, 5x20 mm
Display	
Active screen size (diagonal)	611.3 mm (24.1")
Active screen size (W x H)	518.4 mm x 324.0 mm (20.41" x 12.76")
Resolution	2 MP (1920 x 1200)
Viewing angle (H, V)	178°
Contrast ratio	1000:1 typical
Laser	
Laser wavelength	488 nm
Images	
Image area	16 x 16 mm
Time to image	approx. 9 seconds (for preview mode) approx. 2 min 30 s (for acquisition mode)
Operating Conditions	
Temperature	15..35 °C

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Humidity	30-75 % (non-condensing)
Pressure	80-106 kPa
Transport Conditions	
Temperature	-20-60 °C
Humidity	30-80 % (non-condensing)
Pressure	70-106 kPa
Storage Conditions	
Temperature	0-60 °C
Humidity	30-80 % (non-condensing)
Pressure	70-106 kPa

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14.2. Electromagnetic Compatibility

The Histolog™ Scanner complies with the emission and immunity requirements of IEC 61326-2-6.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The Histolog™ Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog™ Scanner should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Histolog™ Scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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14.3. Electromagnetic immunity

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Histolog™ Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog™ Scanner should ensure that it is used in such an environment.			
Immunity test	IEC 61326-2-6 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4 kV contact ±2, ±4, ±8 kV air	±4 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±1 kV for power supply lines ±0.5 kV for input/ output lines	± 1 kV for power supply lines Complies (Not applicable)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	0% UT (100% dip in UT) for 1 cycle 40% UT (60% dip in UT) for 0.1 s 70% UT (30% dip in UT) for 0.5 s <5% UT (>95% dip in UT) for 5 s	0% UT (100% dip in UT) for 1 cycle 40% UT (60% dip in UT) for 0.1 s 70% UT (30% dip in UT) for 0.5 s 0% UT (100% dip in UT) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Histolog™ Scanner requires continued operation during power mains interruptions, it is recommended that the Histolog™ Scanner be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies (Does not contain any devices susceptible to magnetic fields)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical

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			commercial and/or hospital environment.

NOTE The electromagnetic environment should be evaluated prior to operation of the device.

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Histolog™ Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog™ Scanner should ensure that it is used in such an environment.			
Immunity test	IEC 61326-2-6 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 1 GHz 3 V/m 1.4 GHz to 2 GHz 1 V/m 2 GHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 * \sqrt{P}$ $d = 1.17 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 * \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency

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			range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Histolog™ Scanner is used exceeds the applicable RF compliance level above, the Histolog™ Scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Histolog™ Scanner.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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14.4. Recommended separation distance

Recommended separation distances between portable and mobile RF communications equipment and the Histolog™ Scanner			
The Histolog™ Scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the Histolog™ Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Histolog™ Scanner as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter		
Rated maximum output power of transmitter W	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12 (0.39 ft.)	0.12 (0.39 ft.)	0.23 (0.75 ft.)
0.1	0.37 (1.21 ft.)	0.37 (1.21 ft.)	0.74 (2.43 ft.)
1	1.17 (3.84 ft.)	1.17 (3.84 ft.)	2.33 (7.64 ft.)
10	3.70 (12.14 ft.)	3.70 (12.14 ft.)	7.39 (24.25 ft.)
100	11.70 (38.39 ft.)	11.70 (38.39 ft.)	23.30 (76.44 ft.)
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.			

Annexes 2.2 – HistologTM Scanner Traning Material

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Histolog™ Scanner
Training Material

Study code: 2016-CHUV-01
Protocol Nb: 2015-00187
Project supervisor: Dr Olivier Gaide

Location:
CHUV
Département de dermatologie
Avenue de Beaumont, 29
1011 Lausanne

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Table of content

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1. Agenda

Monday November 21st, 2016 - DEVICE INSTALLATION & PRODUCT TRAINING

Timing	Subject	Audience	Trainer
15h30	Installation of the device on-site (60')	N/A.	D. Joss
17h00	Global Product Training based on IFU (30'): • Device set-up • Device operation • Device cleaning and storage • Troubleshooting • Documentation Additional training on tissue preparation (60'): • Tissue handling (preparation, orientation protocol, positioning) • Visualization of the animal histological structures on Histolog™ Scanner images • Visualization of BCC Histolog™ Scanner images vs. H&E	*All team members involved in the use of the device*	F. Schmitt D. Joss
18h30	Optional: General planning & discussion if needed (30') (dates, samples collection, side tests)	Project Supervisor	F. Schmitt

2. Training objectives

The participant will be able to:

- Understand all the components of the Histolog™ Scanner.
- Use the Histolog™ Scanner and its components in easy, secure and comfortable way.
- Understand the functionalities of the Graphical User Interface and appropriately use them.
- Realize the installation and removal of the system within the regular use.
- Realize proper tissue handling, positioning and recommended tissue staining procedures.
- Recognize and understand errors/problems that might occur, know how to troubleshoot and when to contact SamanTree Medical technical service.
- Understand the cleaning and decontamination methods of the device.
- Delete and download images from the system.

SamanTree Medical will provide examples of the correspondence of histological structures seen on Histolog™ Scanner and standard microscopy slides (for internal use only).

3. Documentation Training

Usability Feedback form
Forms are collected for a total of two (2) times during the research, at the beginning, and at the end. According to a specific scale, the user must provide a grade as well as its comments. This form is useful for SamanTree Medical to improve device usability within the dedicated workflow of the research project.

Device Defect form
At every issue encountered by the user, a Device defect form must be filled in and sent immediately to SamanTree Medical.

SamanTree's team is available at any moment during the research project in case of issue with the device.
Contact details:
Frederic Schmitt - Clinical Scientist: frederic@samantree.com
Diego Joss - Engineer: diego@samantree.com
Etienne Shaffer - CTO, Engineer: etienne@samantree.com
SamanTree Medical office number: 021 625 09 40

4. Tissue Specimen Imaging

This information is complementary to Section 6.2 of the Instructions for Use (v1.2) provided by SamanTree Medical.

1. Tissue resection and orientation as usually performed by the center.
2. Tissue Specimen Staining, as per Instructions for Use, v1.2 section 6.2.1
    a. Immerse in staining solution
    b. Rince few seconds in PBS
    c. Optional: Remove excess fluid with absorbing towel
3. Tissue Specimen Positioning, as per Instructions for Use, v1.2 section 6.2.2
    a. Surface of interest is facing downside to the optical interface
    b. Tissue centered on dish optical interface
4. Apply tissue flattening load if needed
5. Close dish lid
6. Mount dish on Histolog™ Scanner device, as per Instructions for Use, v1.2 section 6.2.3
7. Start Preview and images acquisition, as per Instructions for Use, v1.2 section 6.4
8. Remove dish from device, as per as per Instructions for Use, v1.2 section 6.2.4

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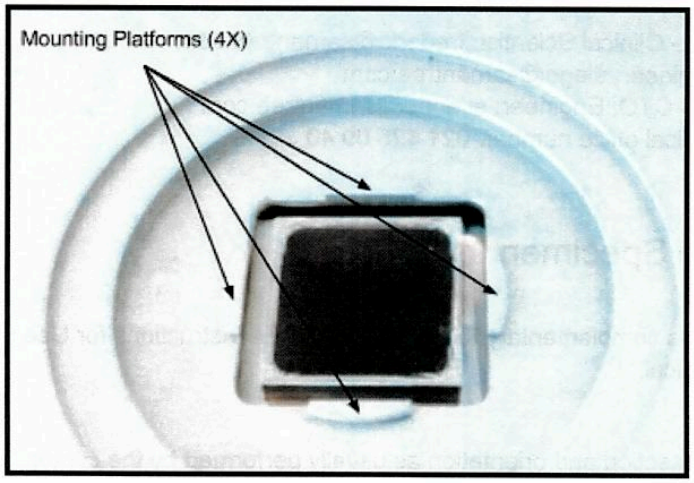
5. Histolog™ Scanner Dish

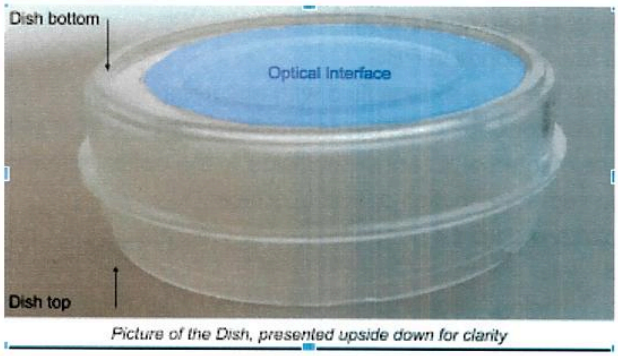
The Histolog™ Scanner is recommended to be used with following third-party dish (the "Dish"):

Manufacturer	Ibidi GmbH
Catalog #	81158

The below information is complementary to section 6.2.3 of the Instruction for Use (1.2).

NOTE The dish optical interface has to rest on all 4 mounting platforms.
Keep in mind that the optical interface is not always centered in the dish.





Picture of the Dish, presented upside down for clarity

Example of a non-centered optical interface

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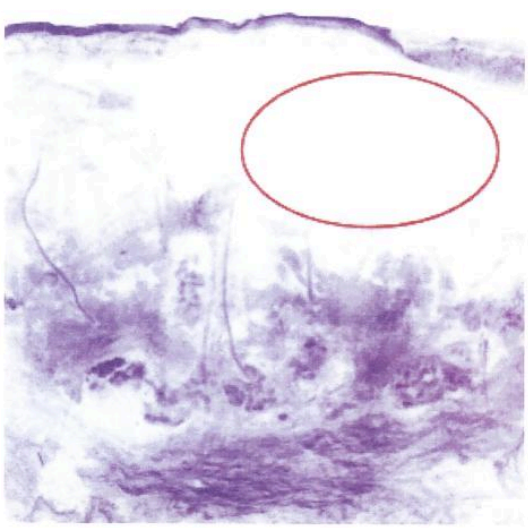
Appendix: Troubleshooting on specimen imaging - Poor image quality (see IFU)

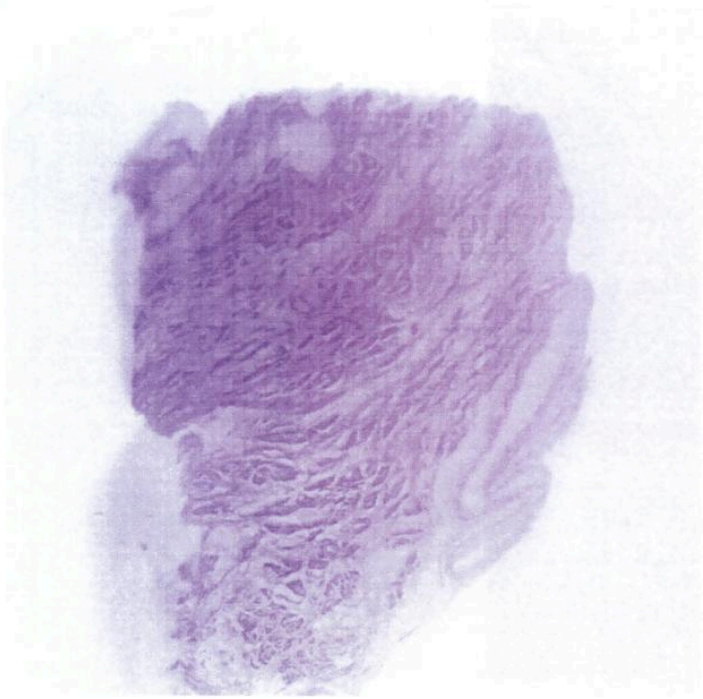
1. Specimen Staining Issue: Signal is too low or some areas are in contact with the optical interface but not visualized



OR

Solution: Apply to the tissue specimen a second tissue staining procedure

2. Dish Positioning: Blurry image with high background around the specimen



Solution: check the correct positioning of the dish on the four (4) pillars as described in the section 5, page 6 of this document and on the section 6.2.3 of the Instructions for Use

3. Moving artefacts

Solution: Sample has moved during the acquisition, launch a new acquisition

4. A grid is seen on the image

Solution: Protective cap of the imaging area has been placed/removed during the acquisition, launch a new acquisition

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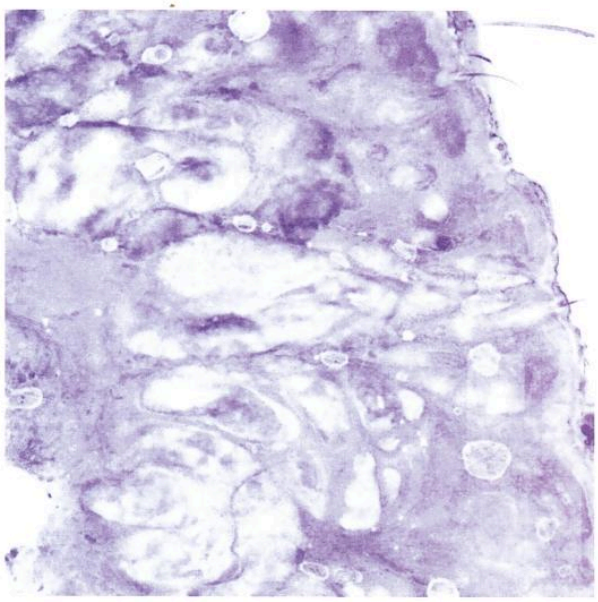
5. Some areas are not in contact with the optical interface of the dish

Solution: Reposition the tissue in the Dish and launch a new acquisition

6. Image is blurry with or without bubbles



Solution: - Make sure the tissue specimen is wiped free of excess fluid by swabbing it gently

- Disposable Histolog™ Dish is dirty, use a new dish to image your tissue specimen
- Tissue flattening system is applying too much pressure on the specimen

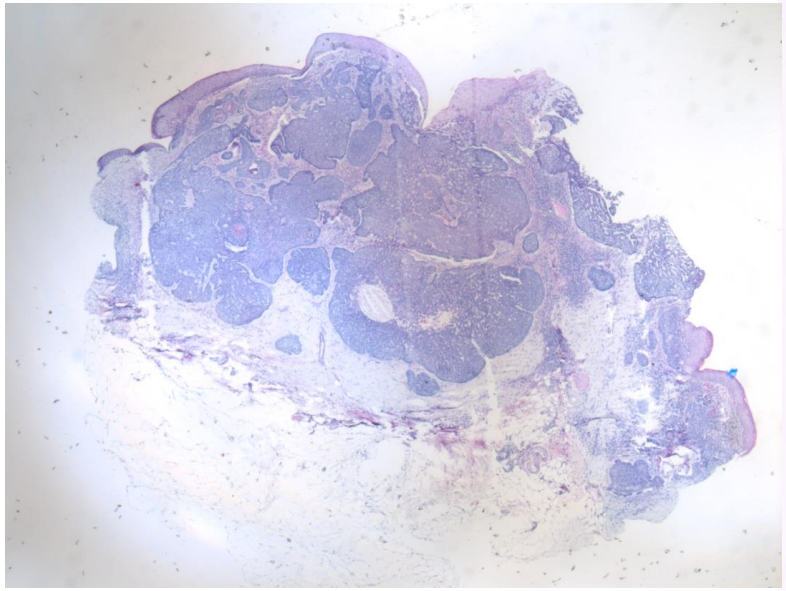
Annexes 3 – Présentation des images

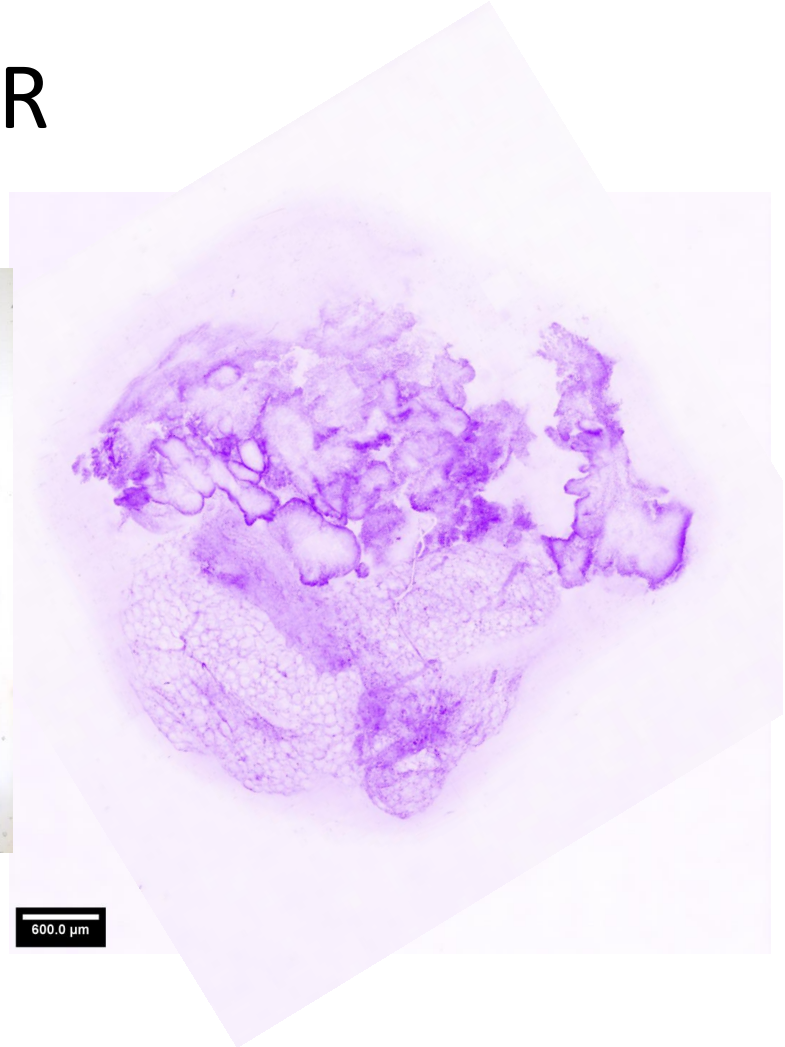
Microscopie sur tissus frais dans la chirurgie de Mohs du carcinome cutané

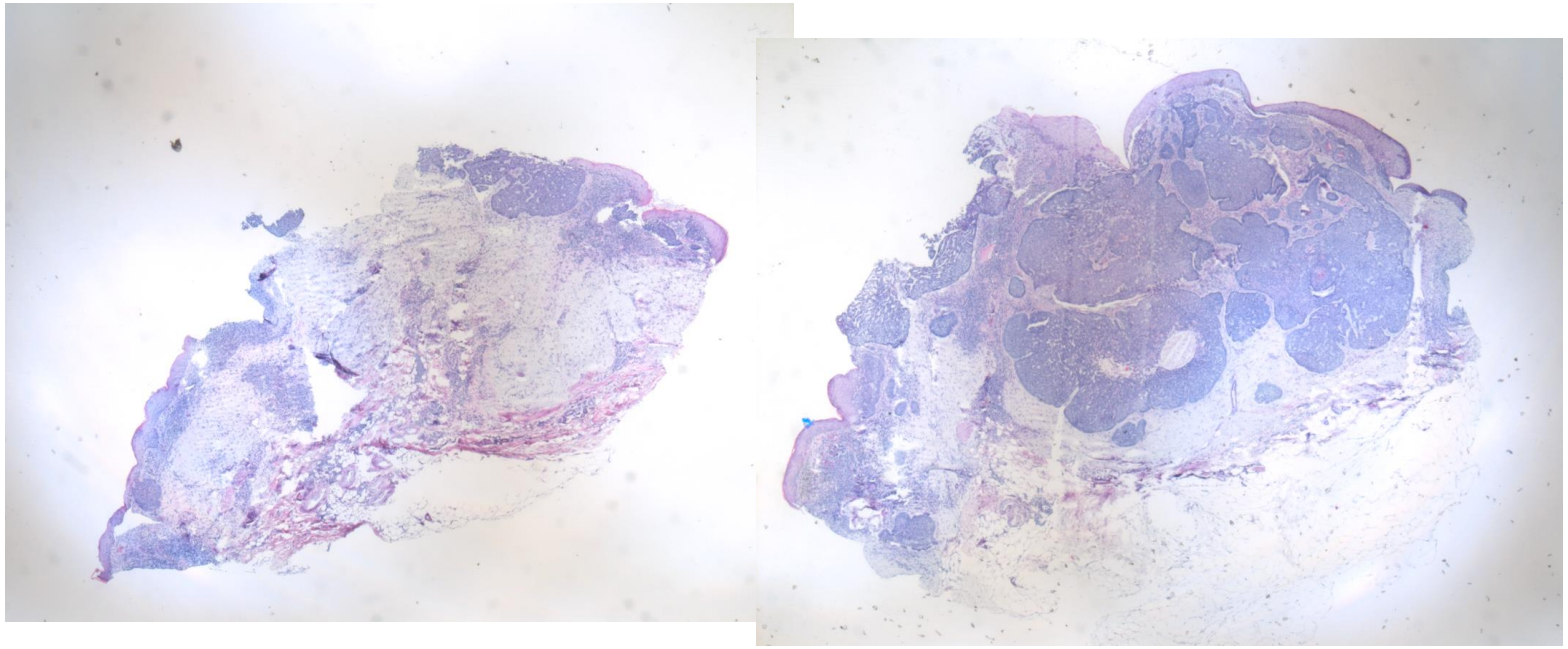
Présentation des images prises

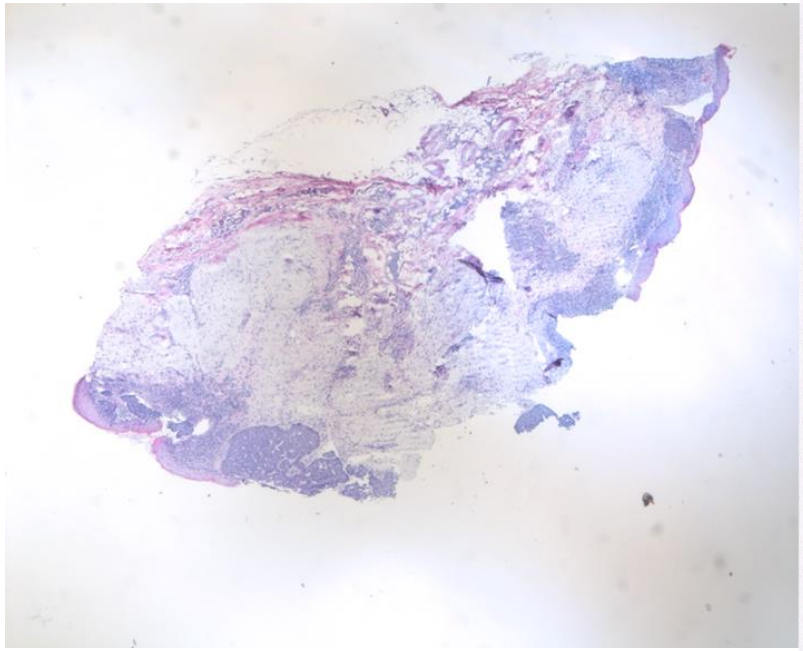
Véronique Matray

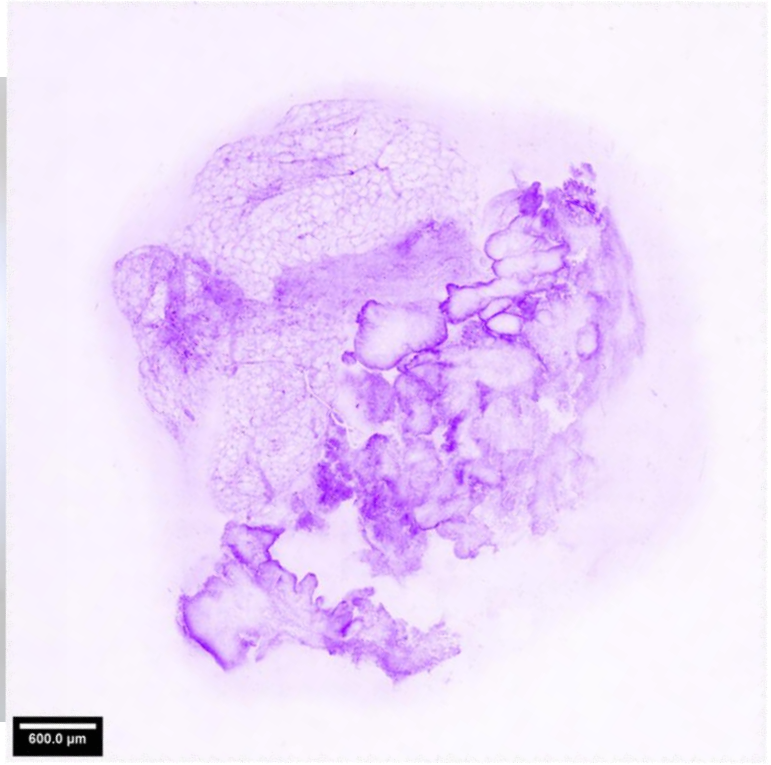
AR



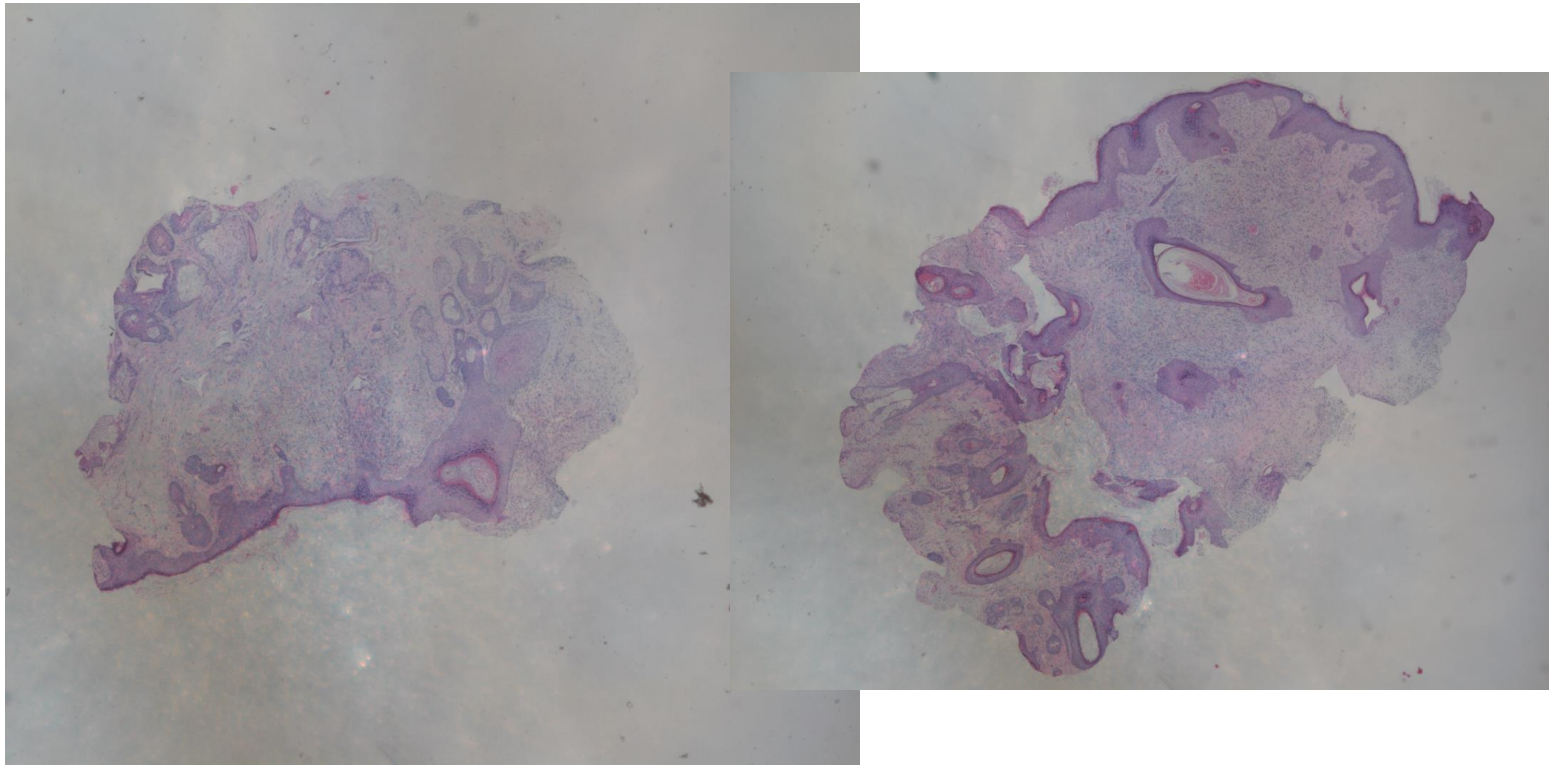


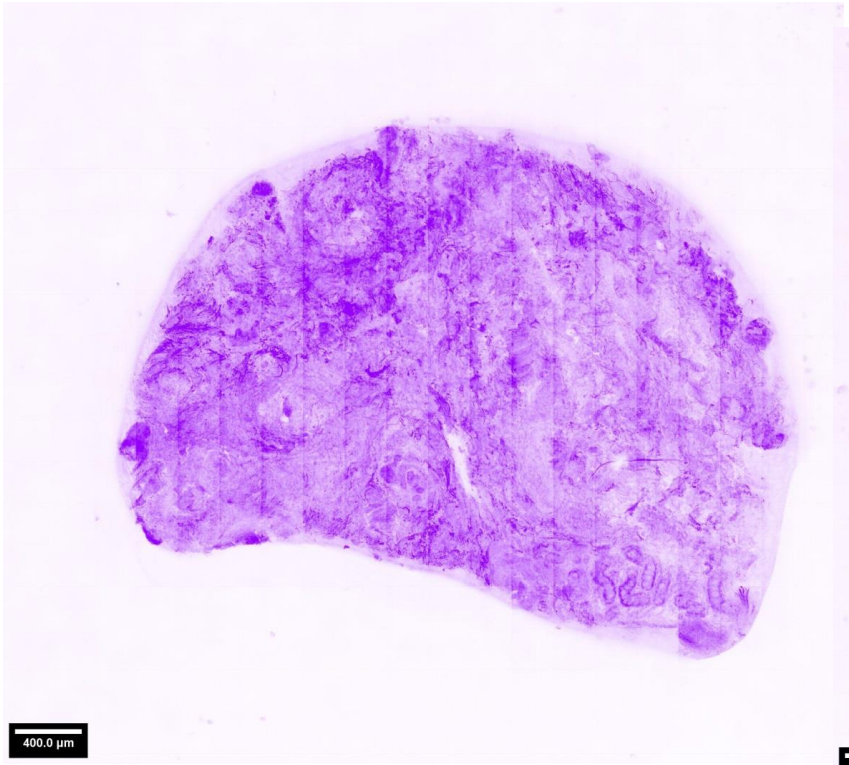





600.0 µm

BF

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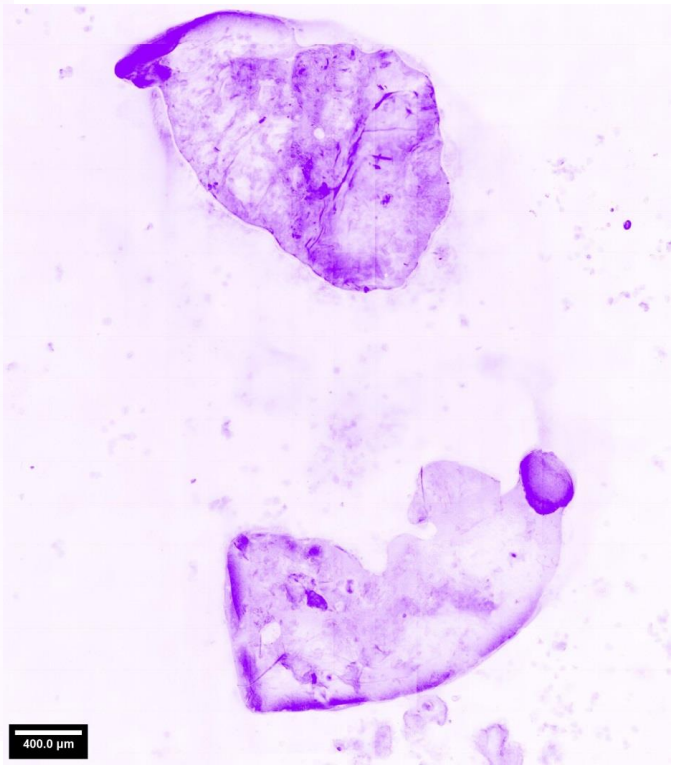
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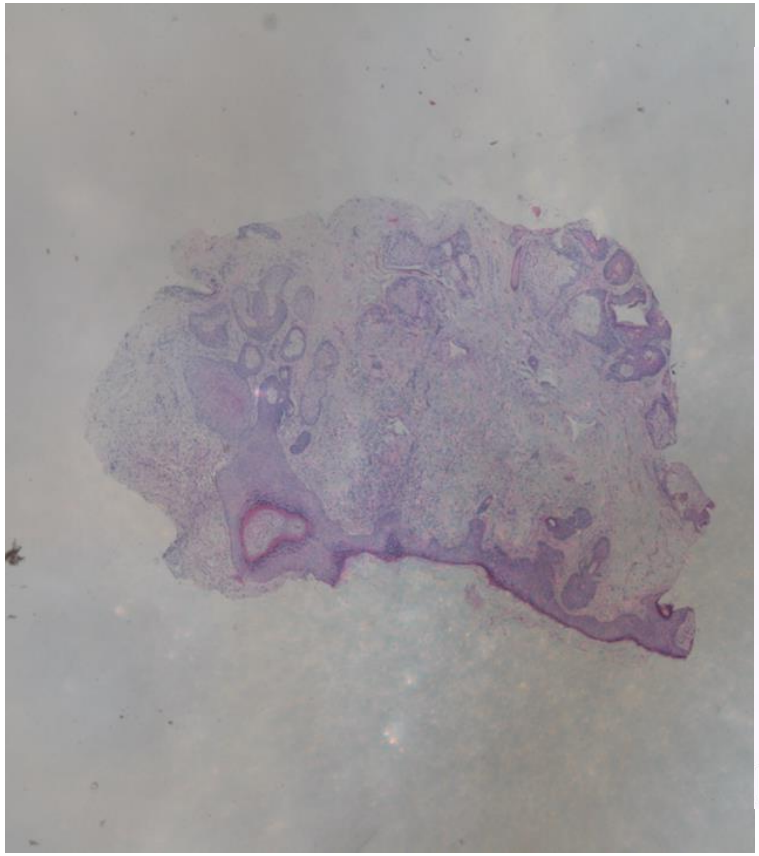

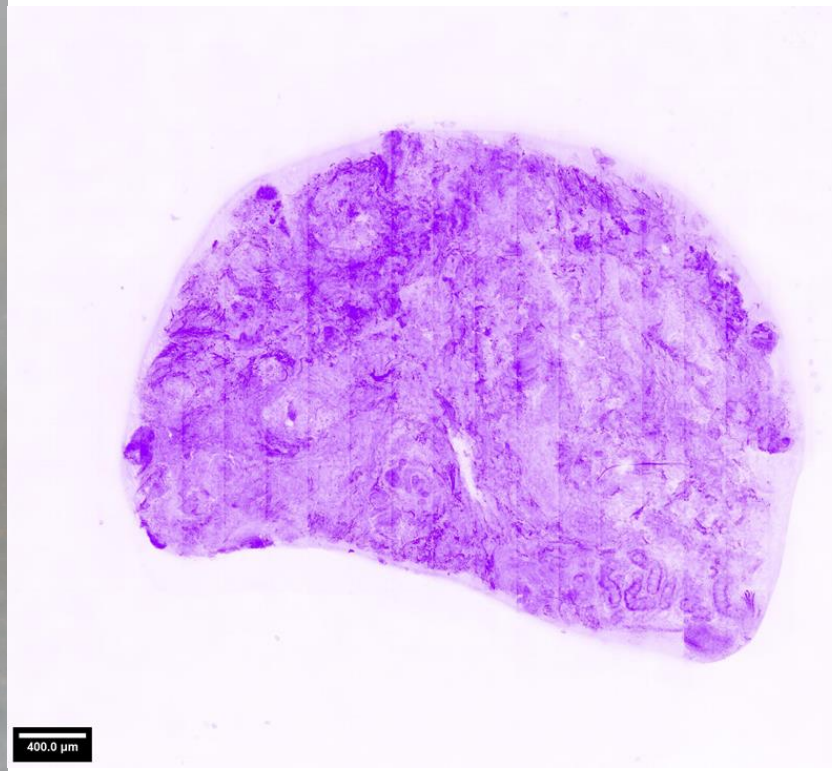
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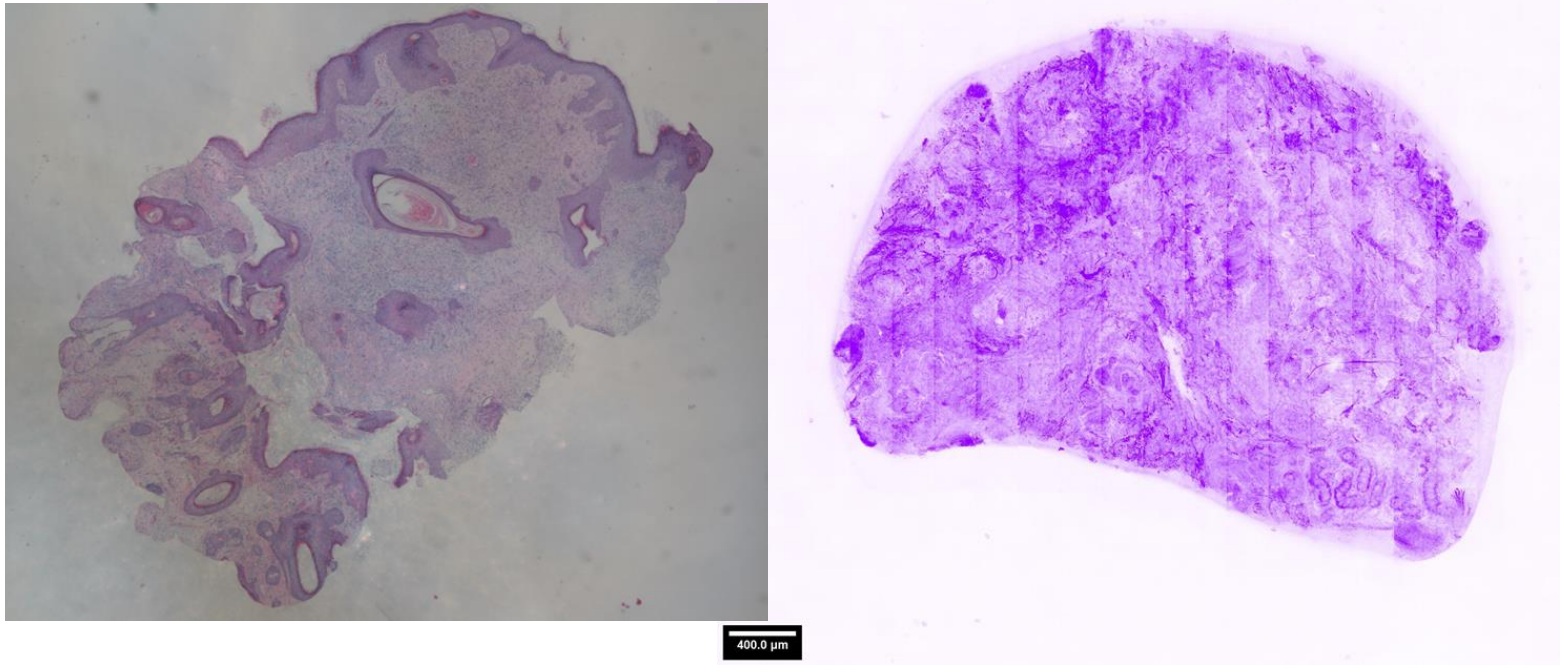
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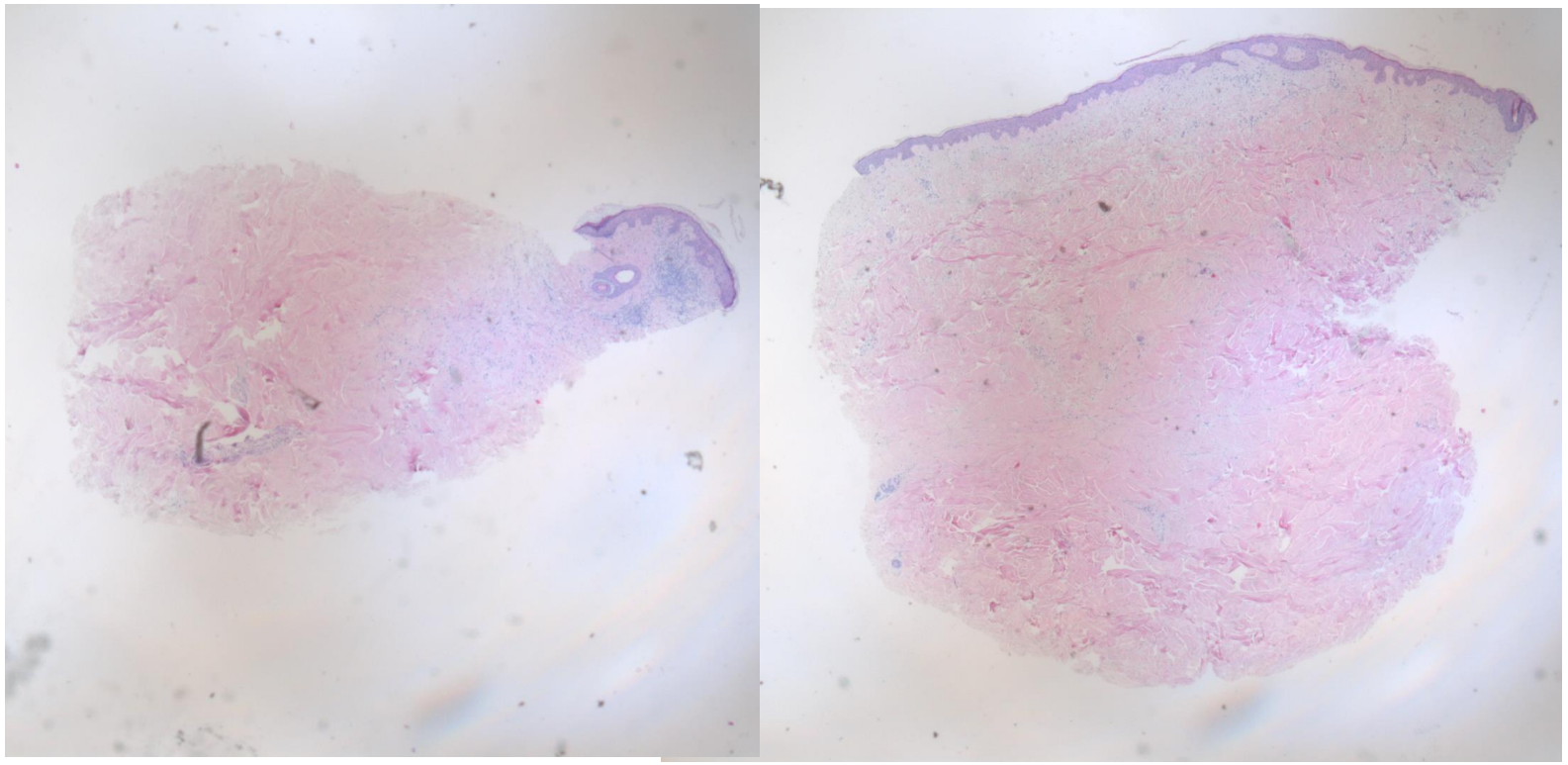

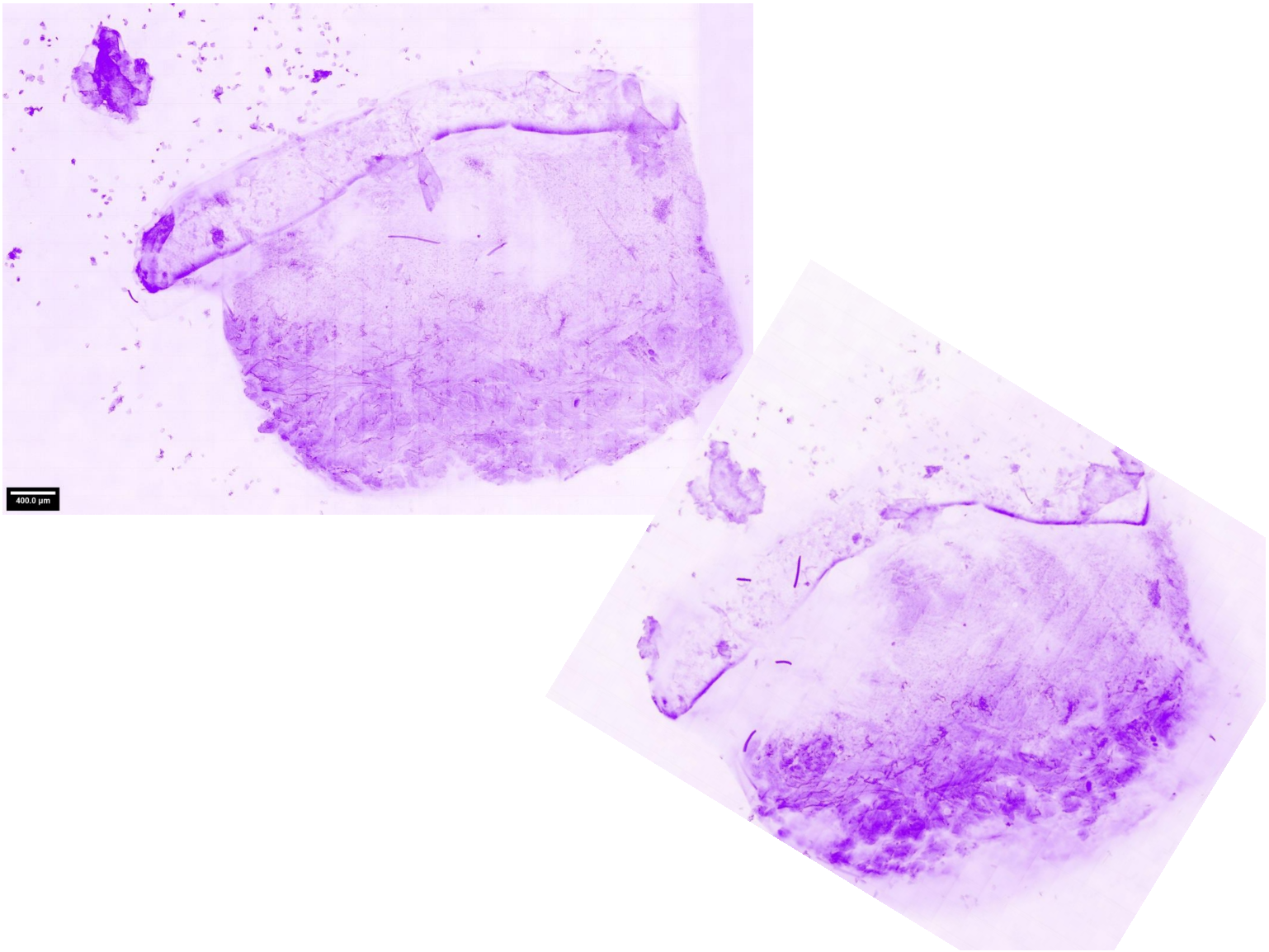
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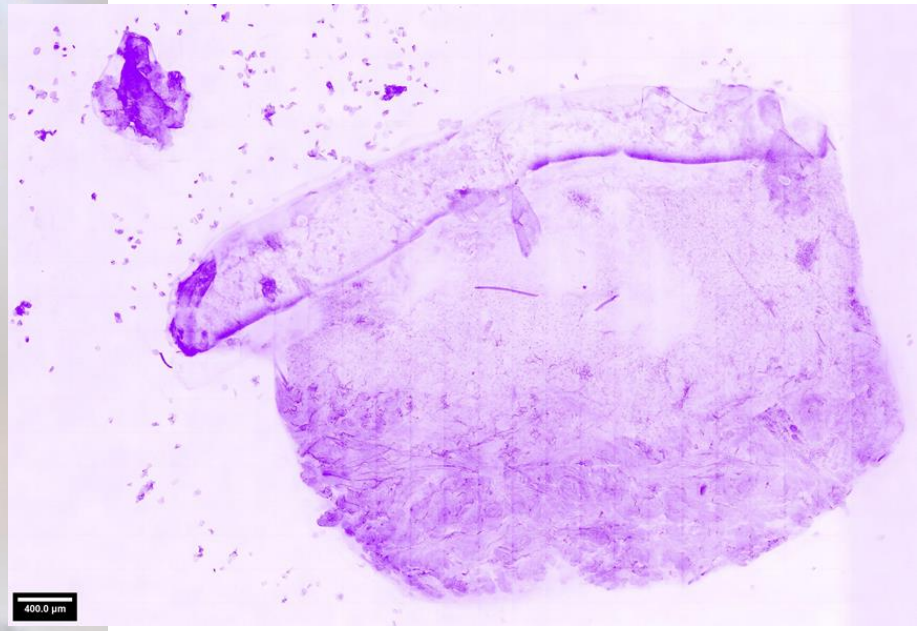
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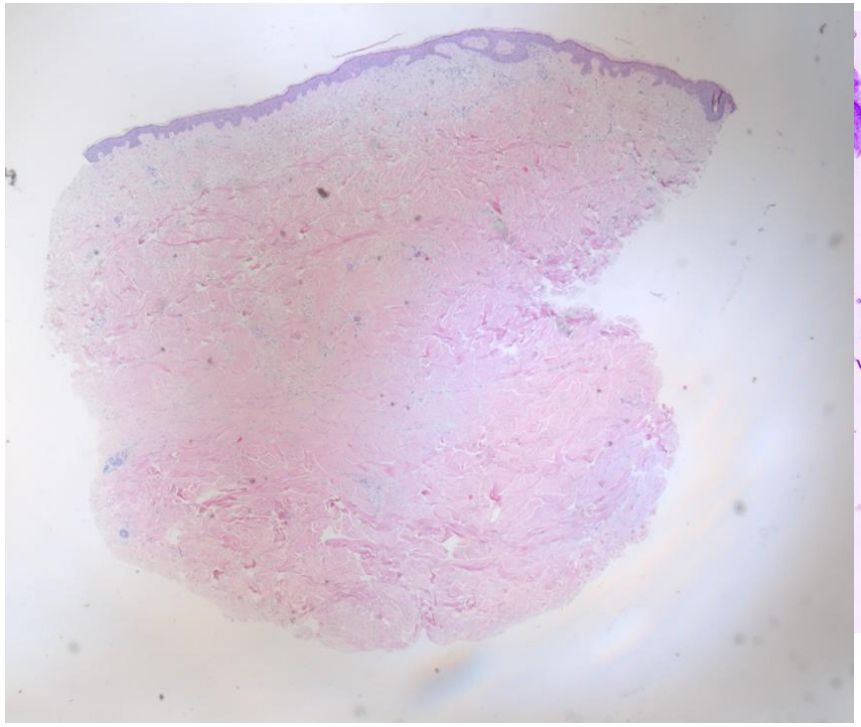

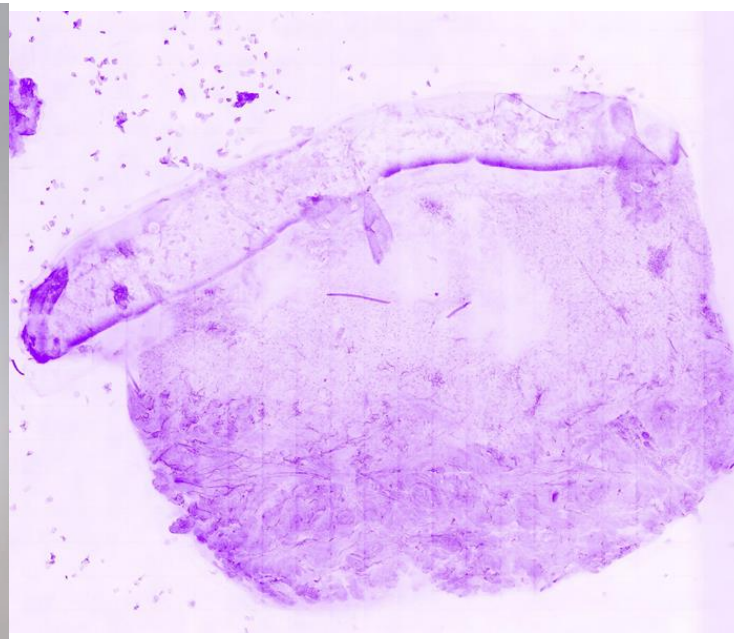

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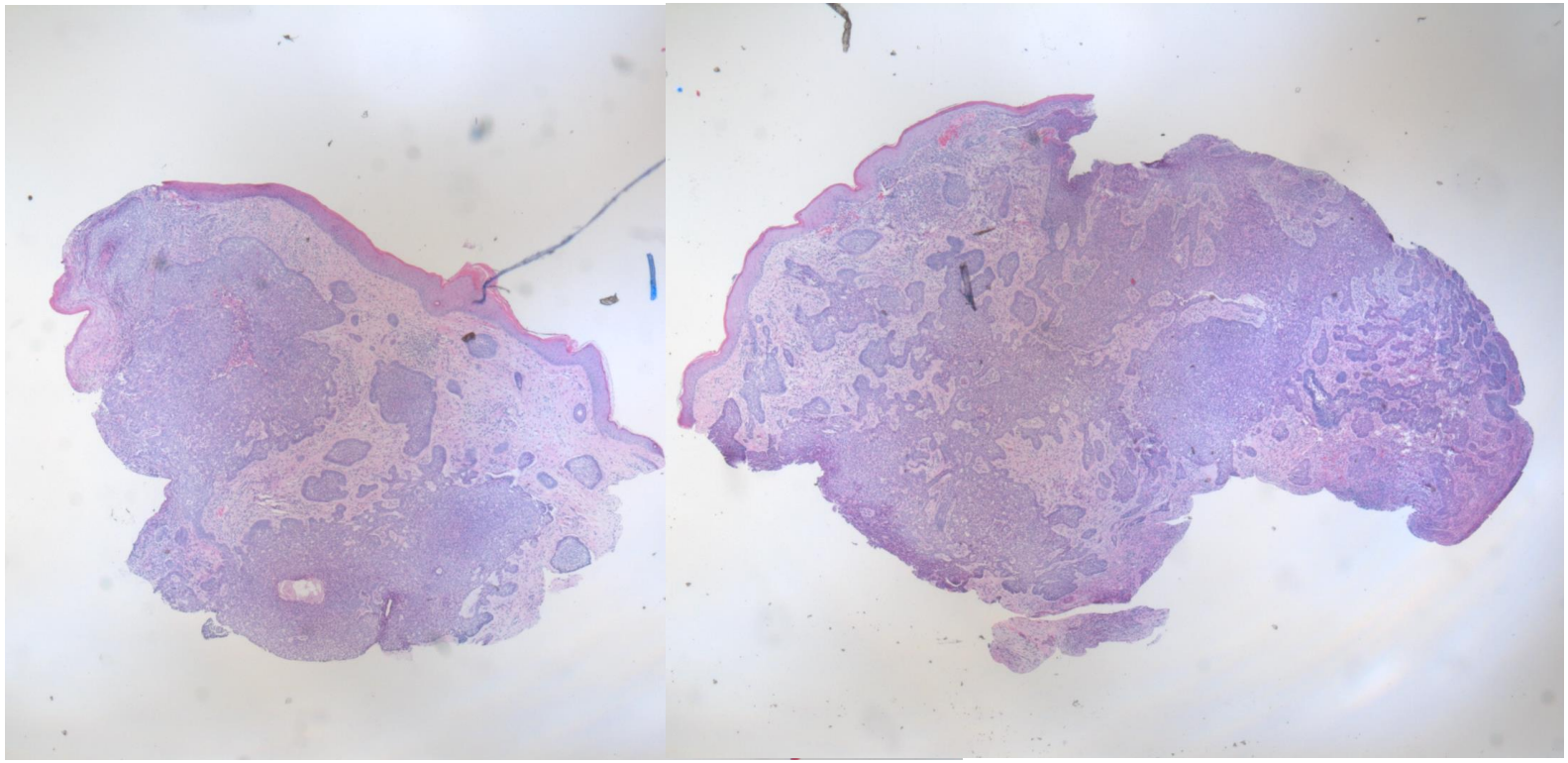

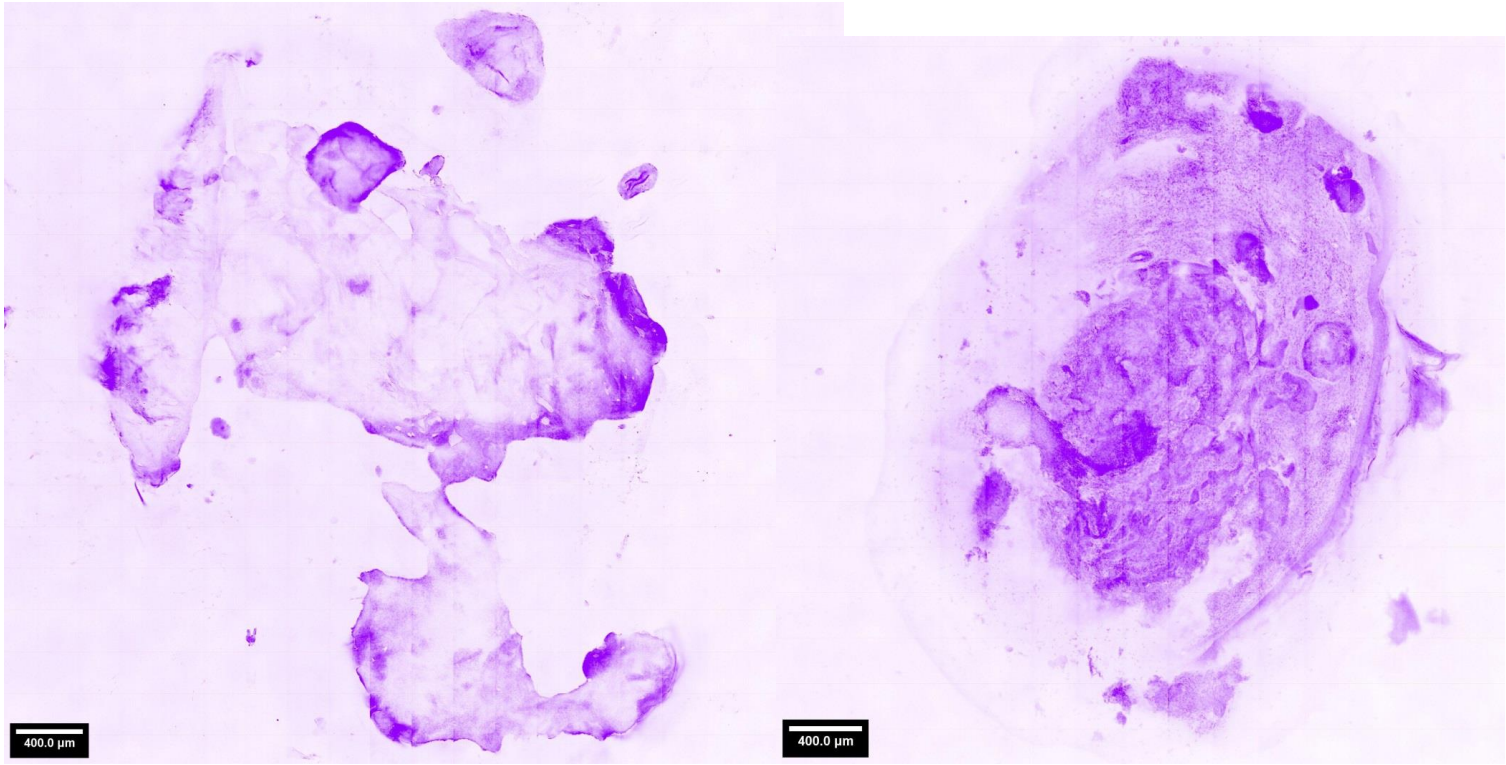
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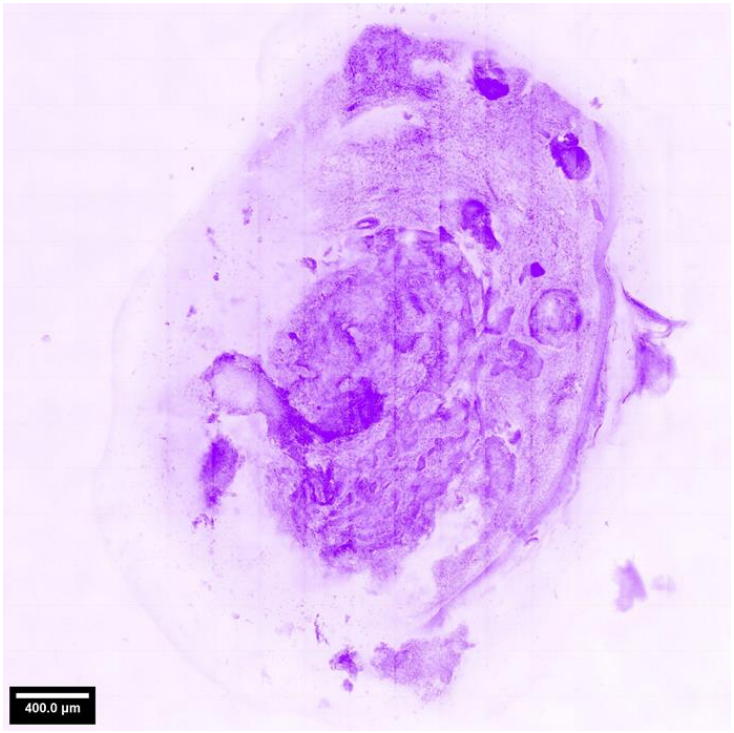
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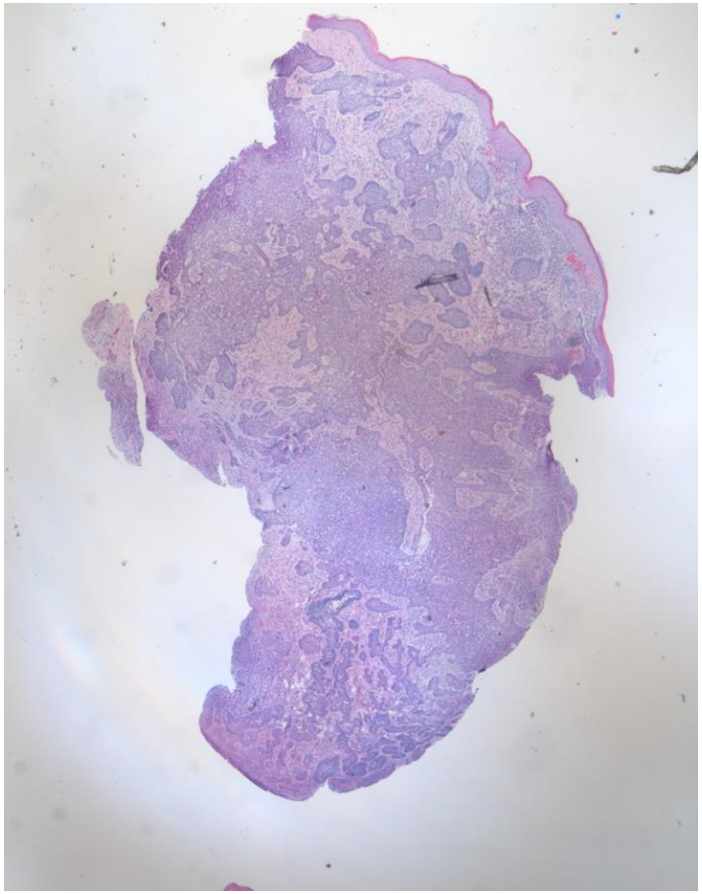

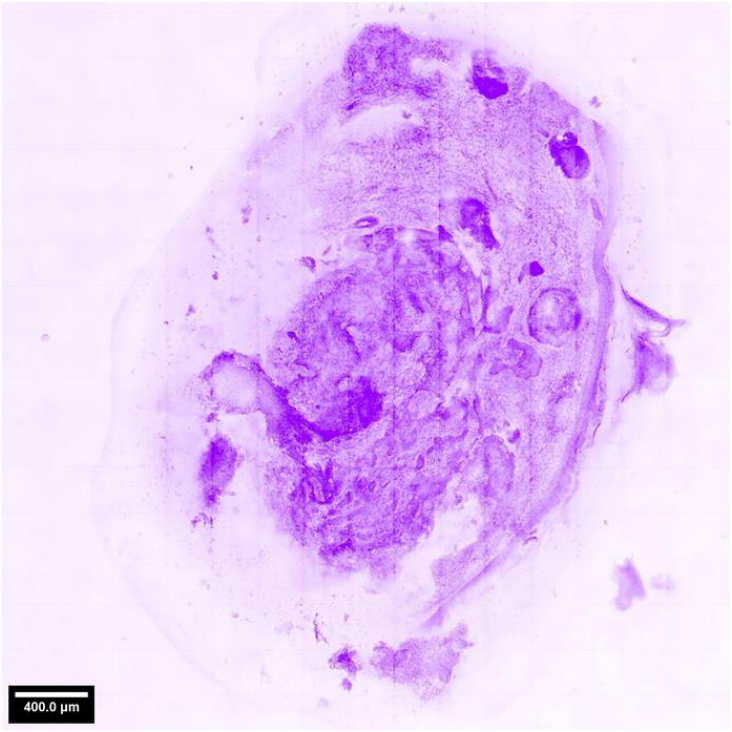
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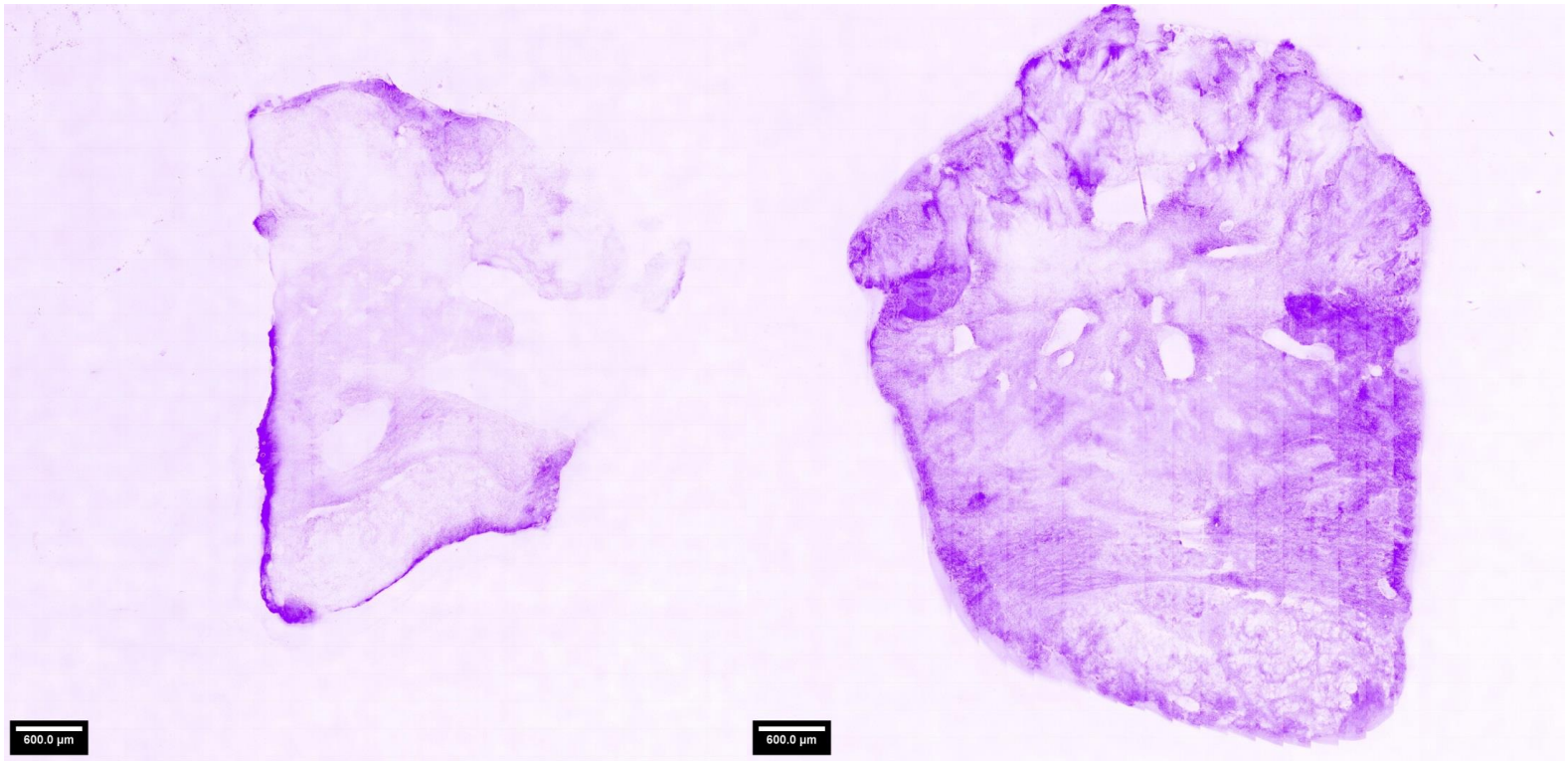
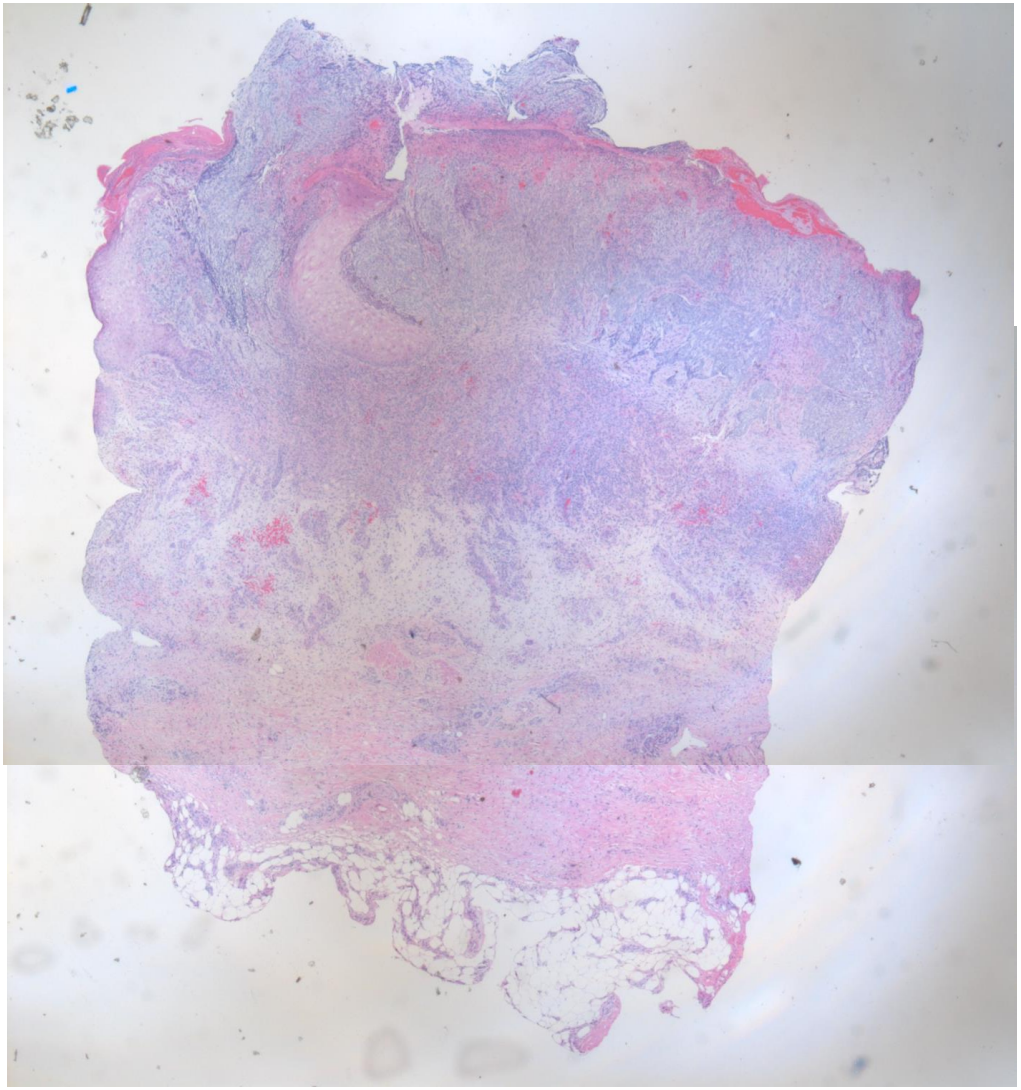
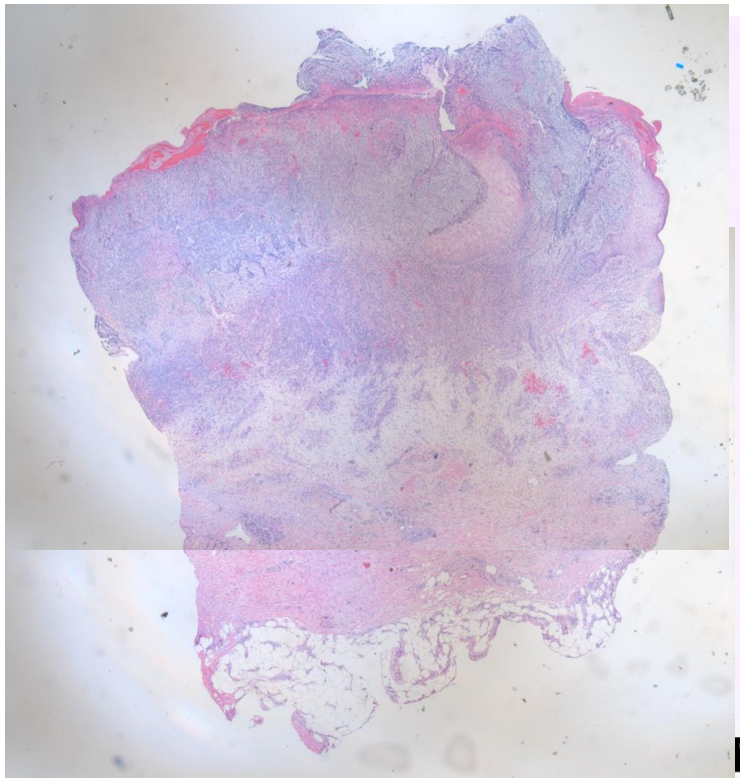
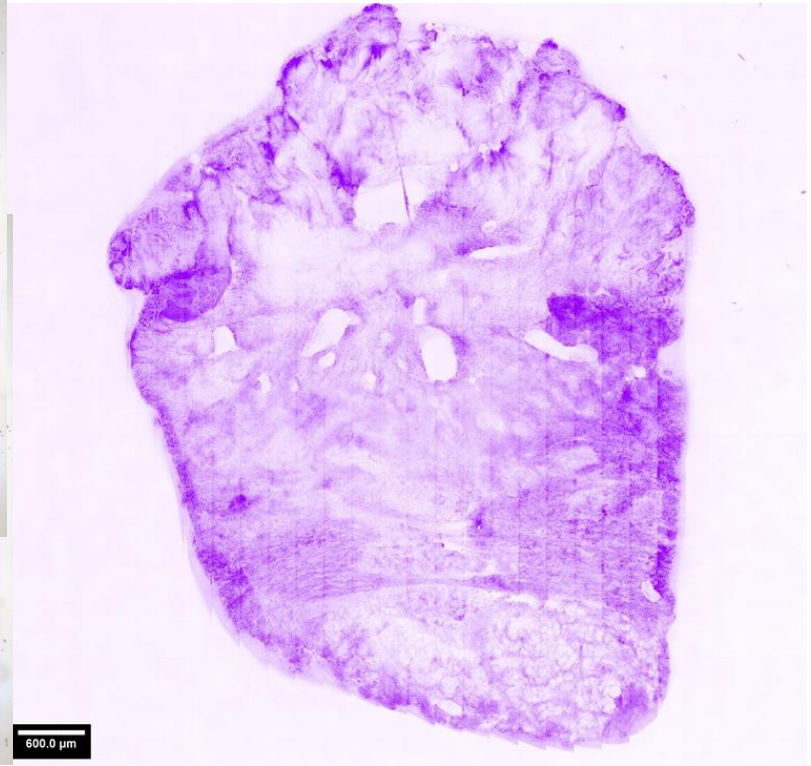
CF





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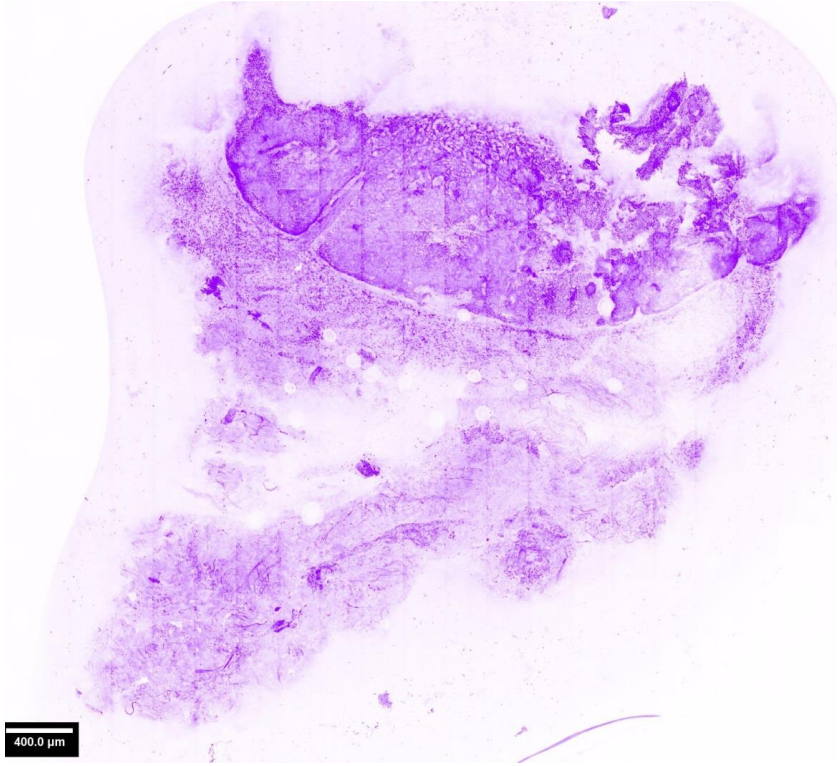
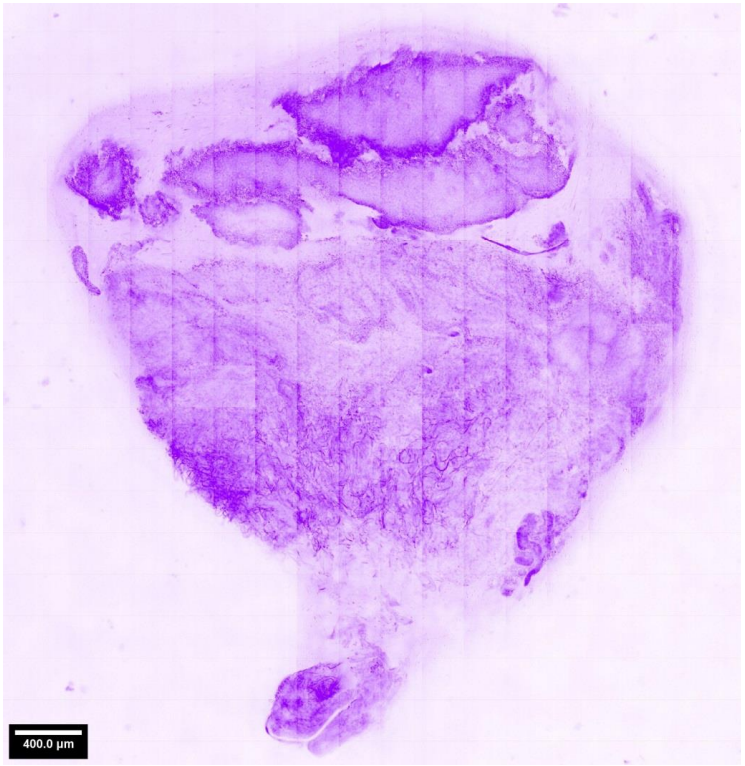
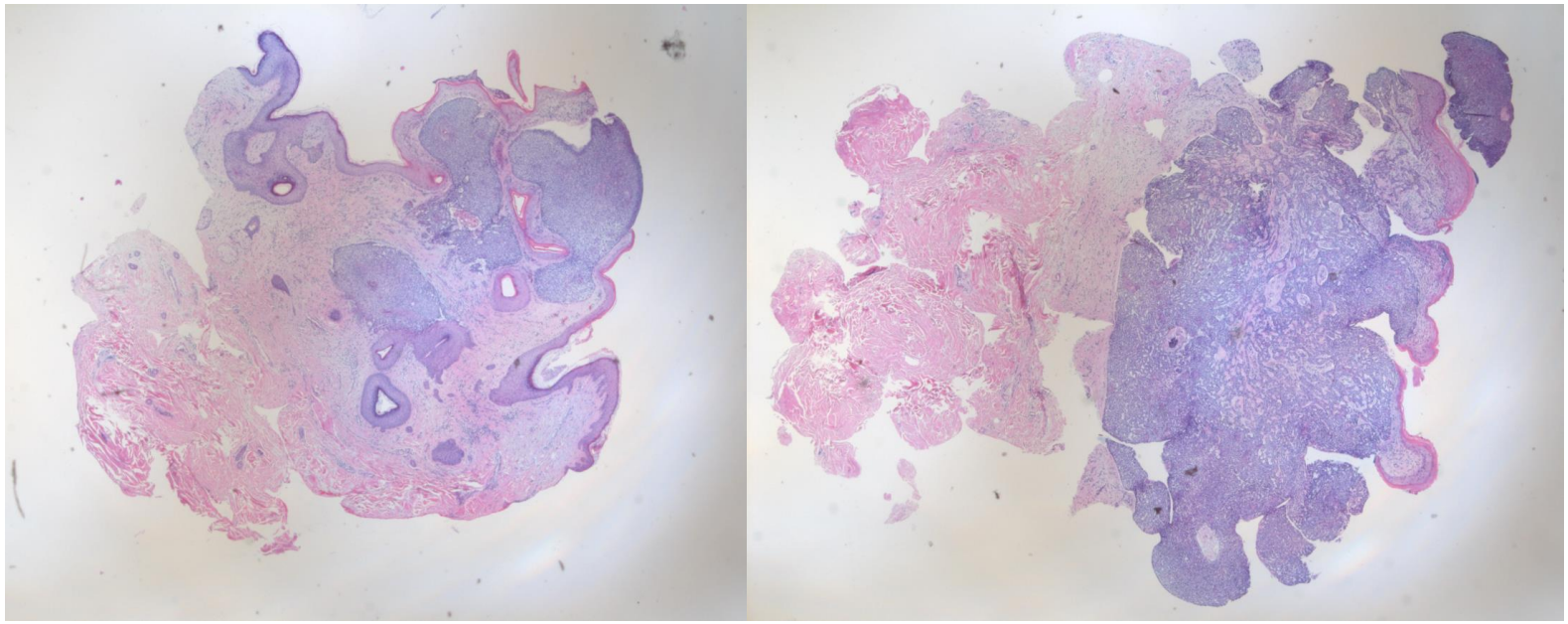
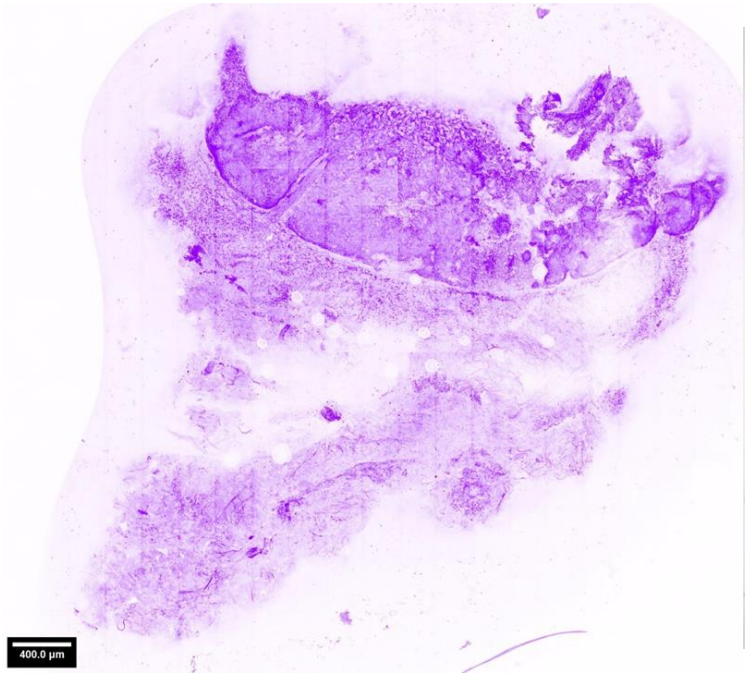
VDF





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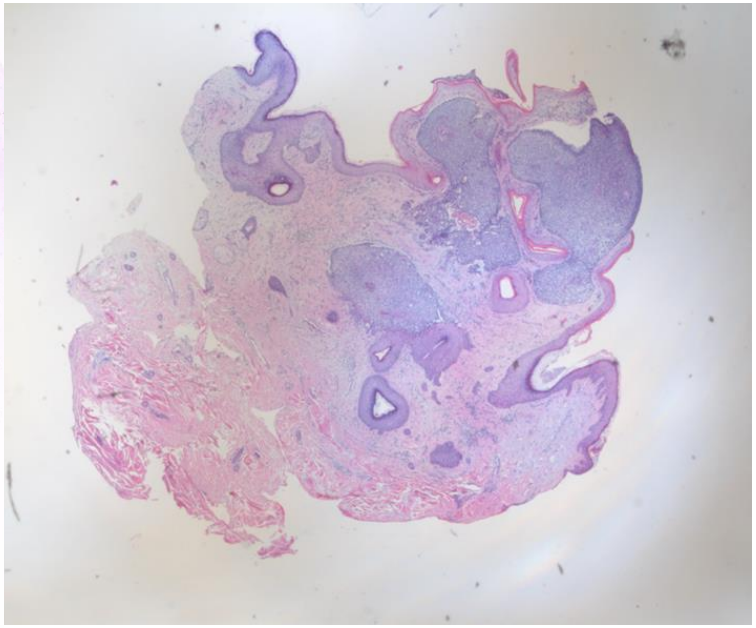

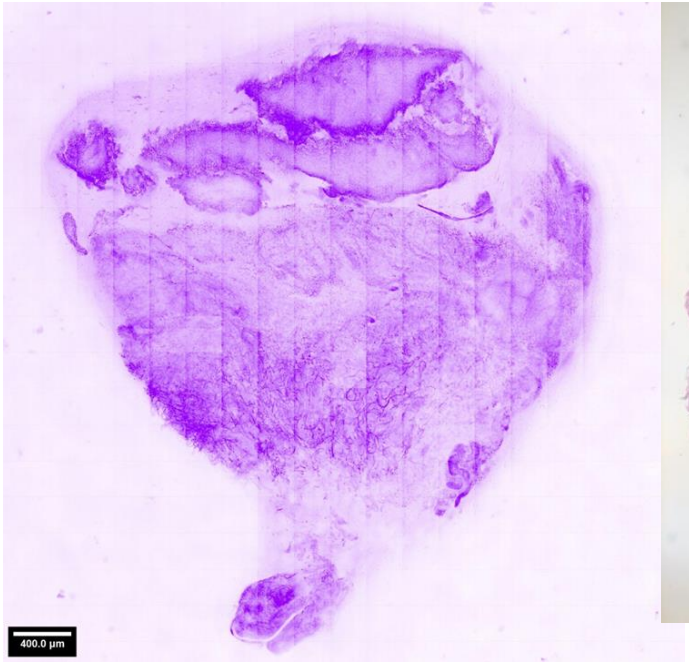
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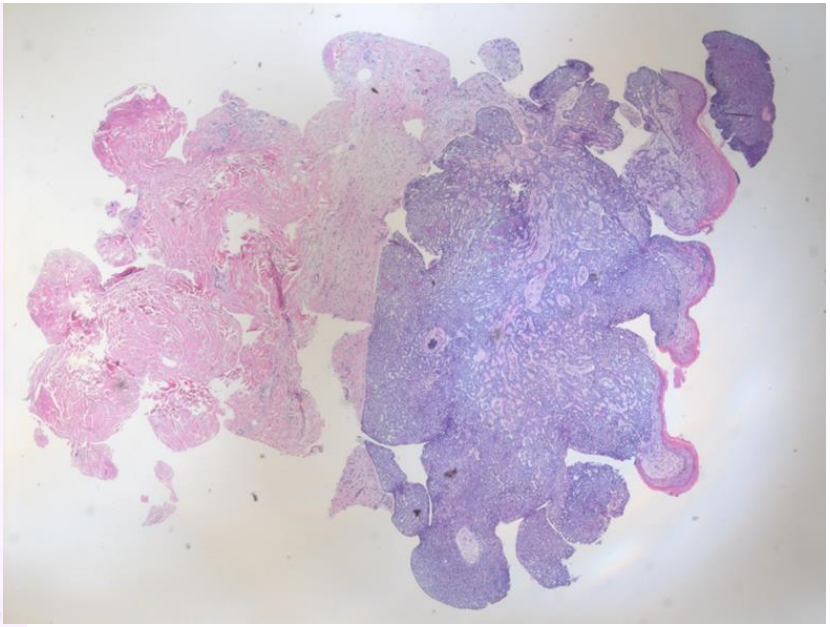

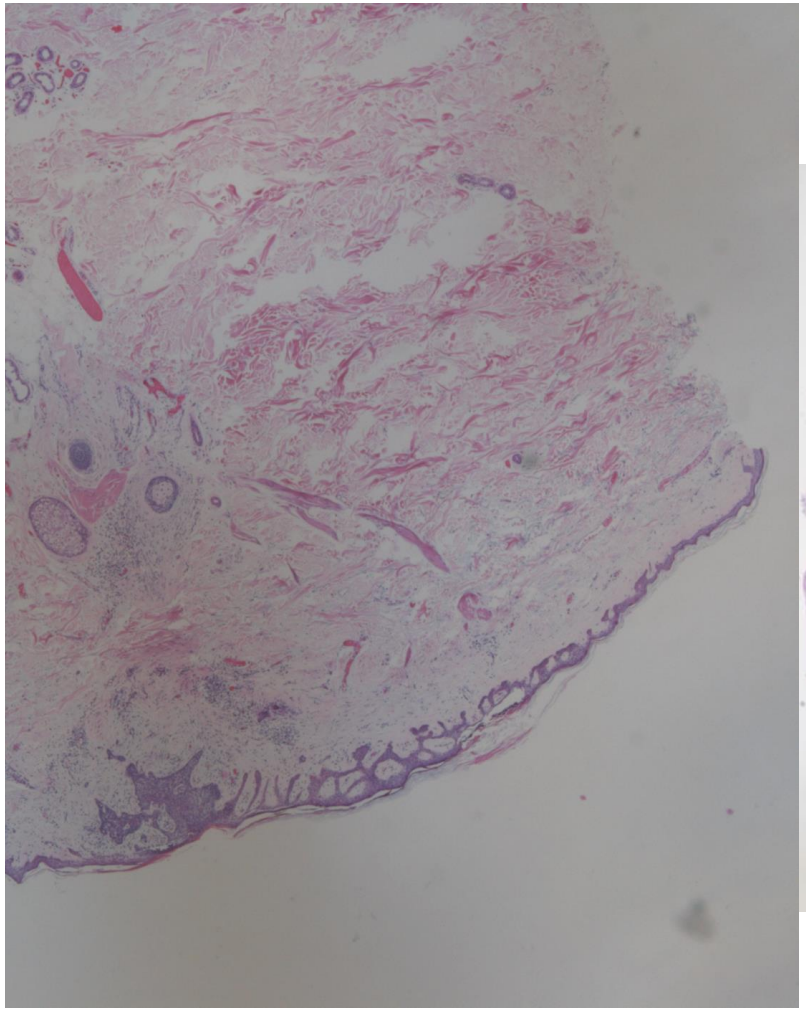

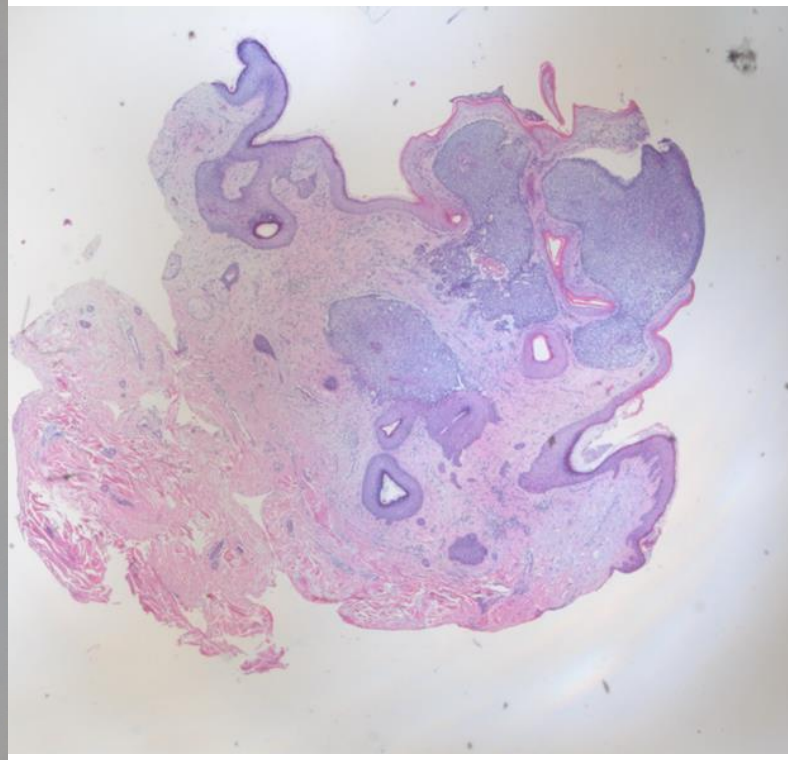

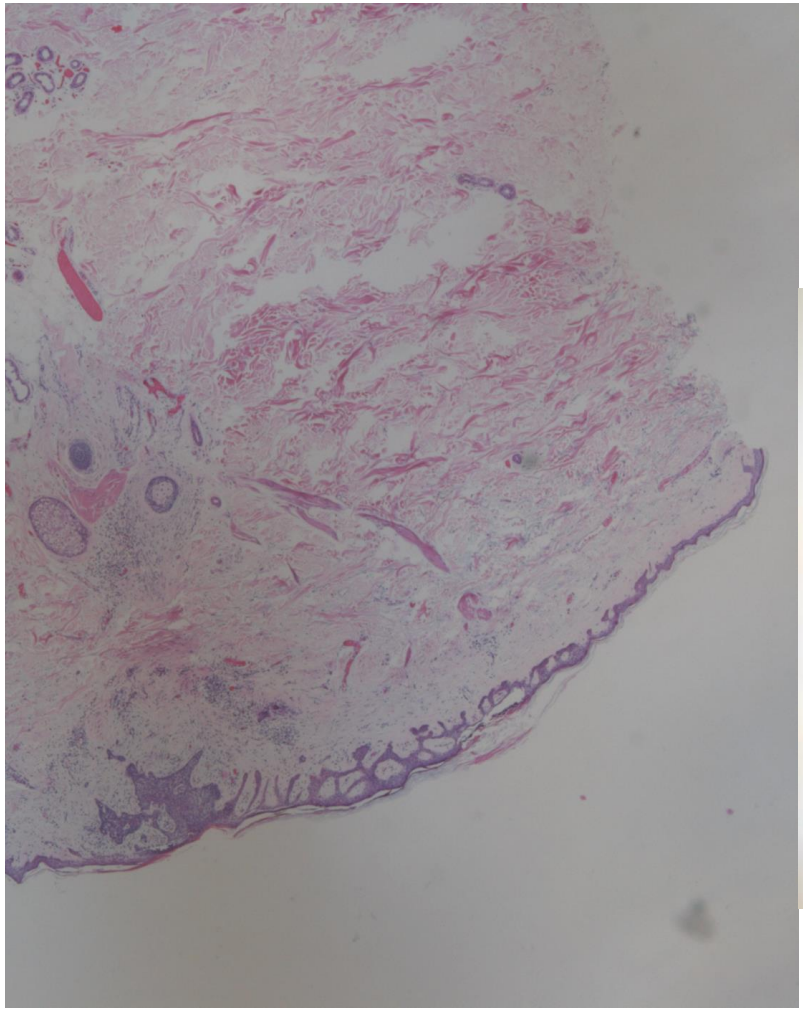

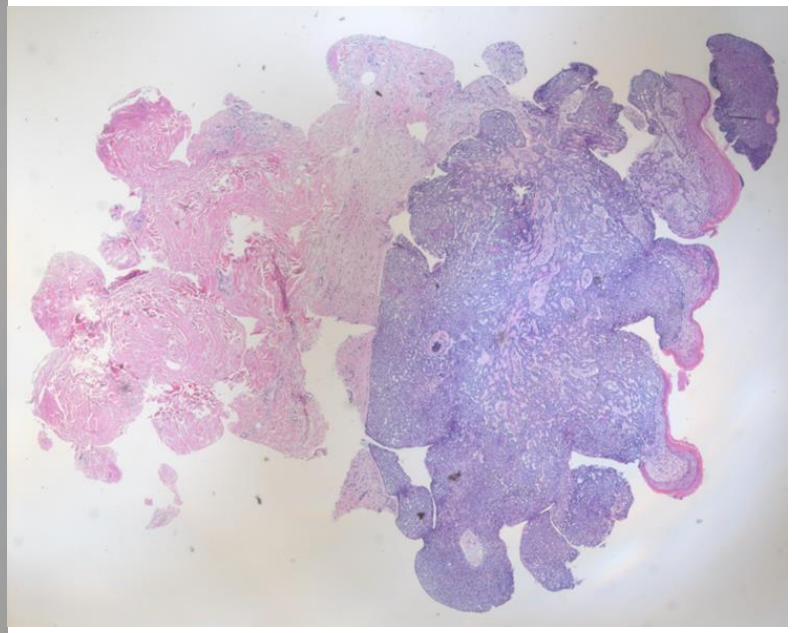

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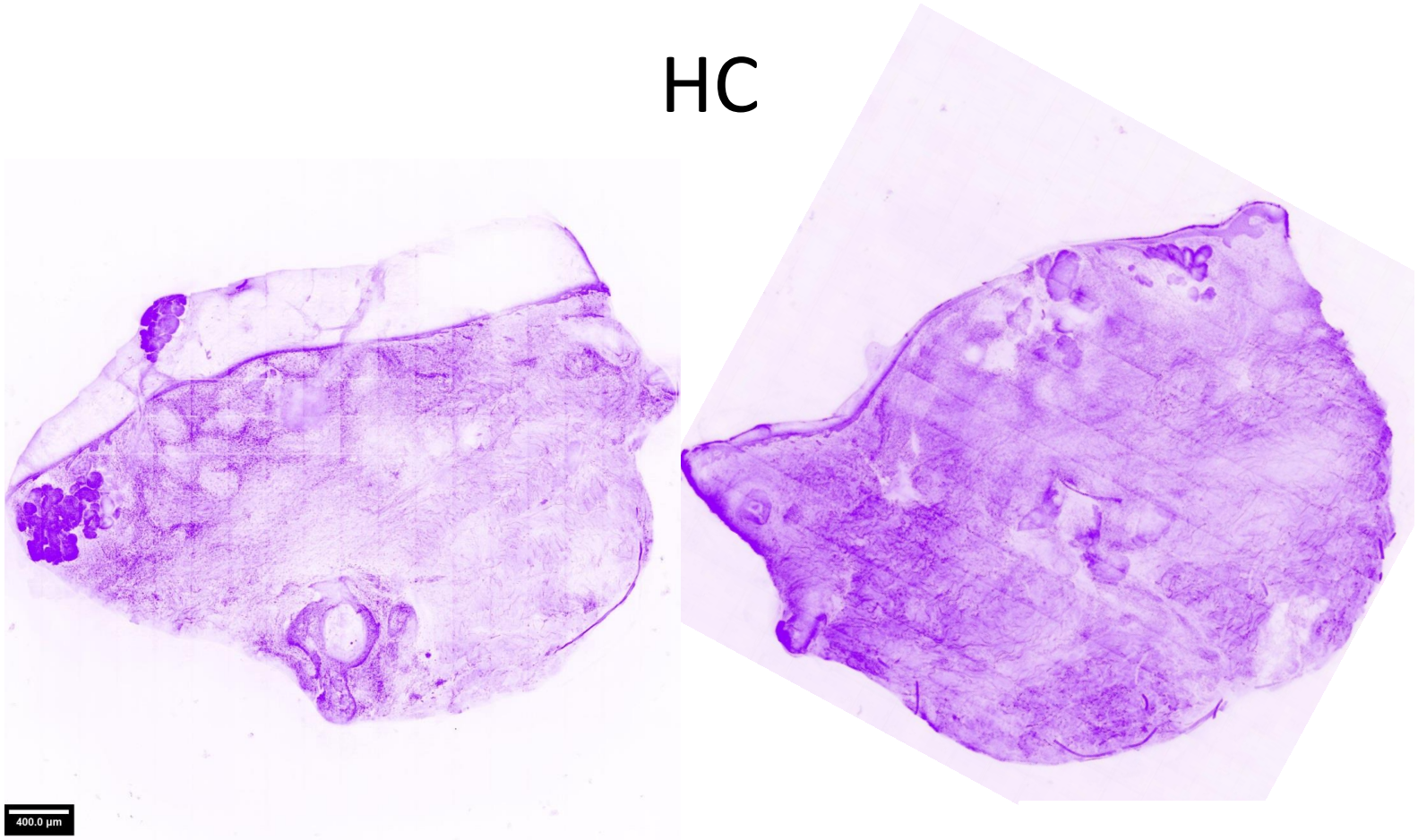

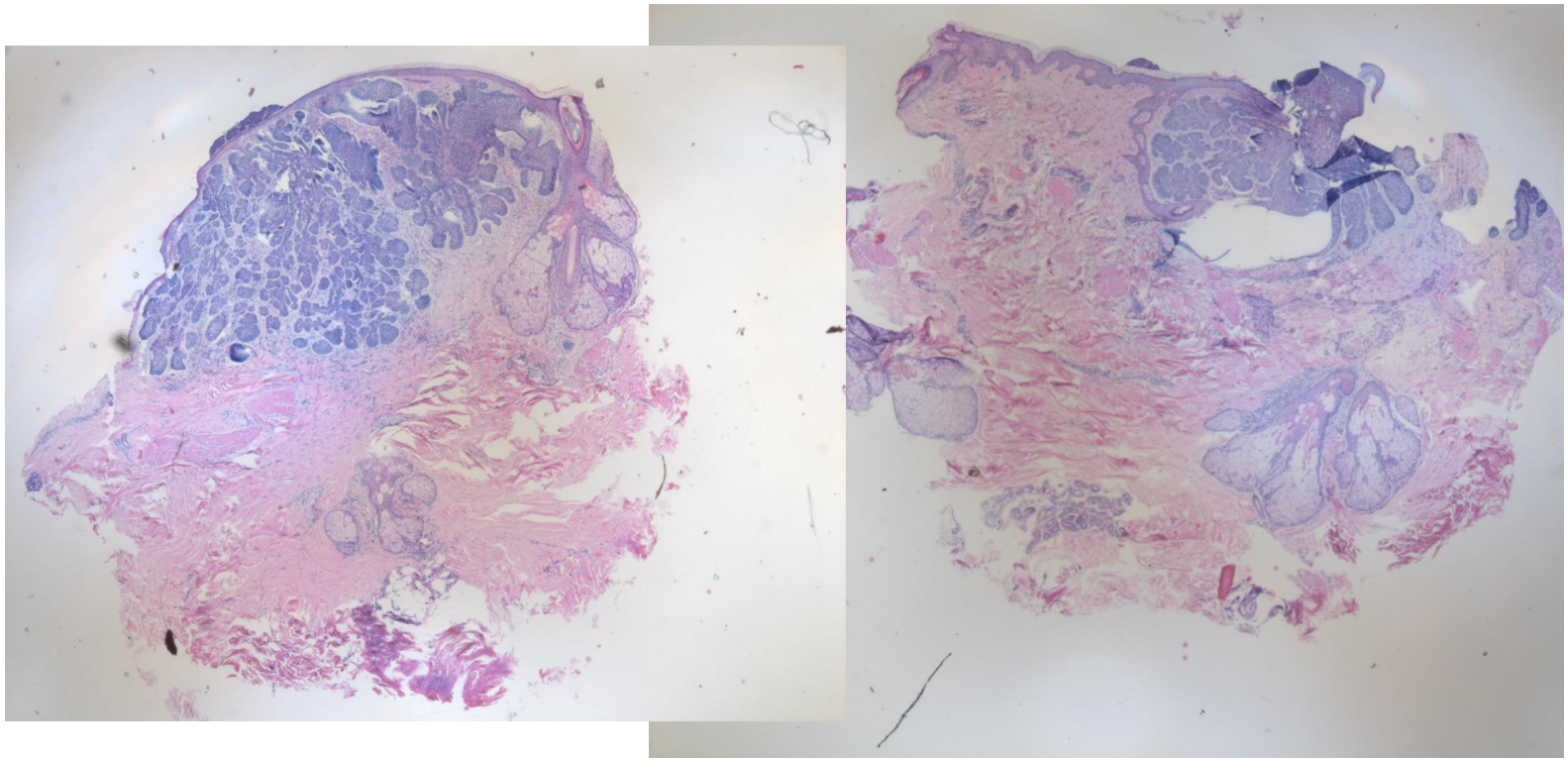

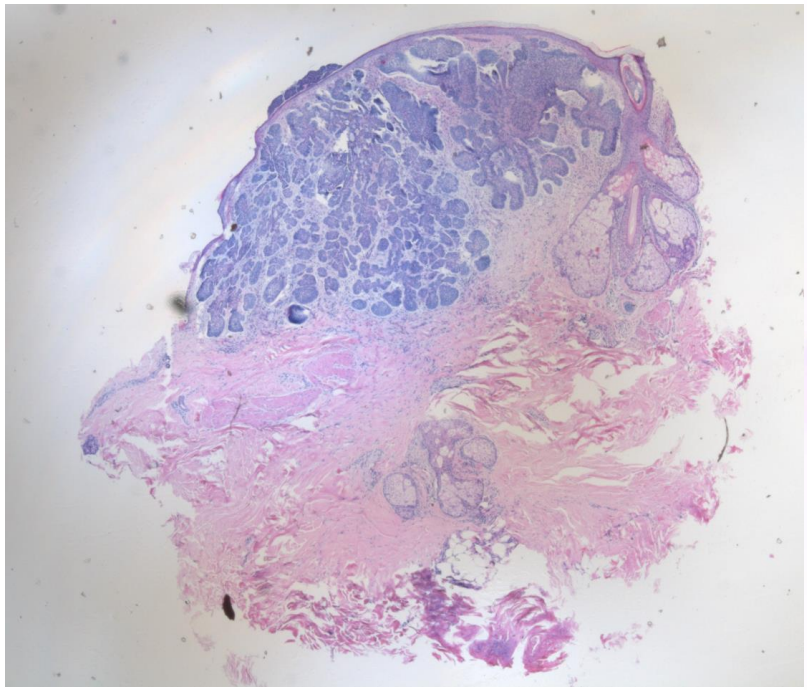

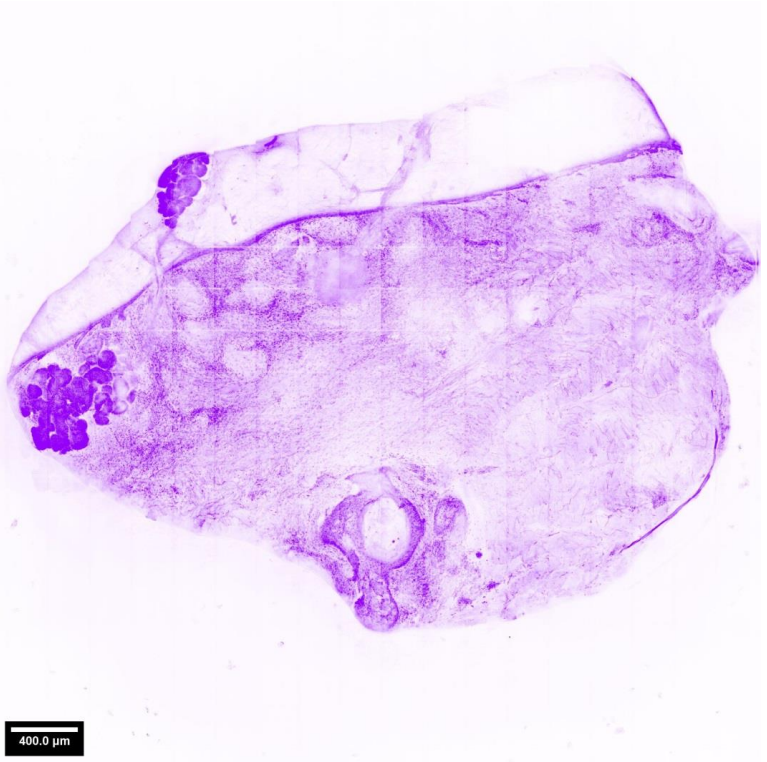
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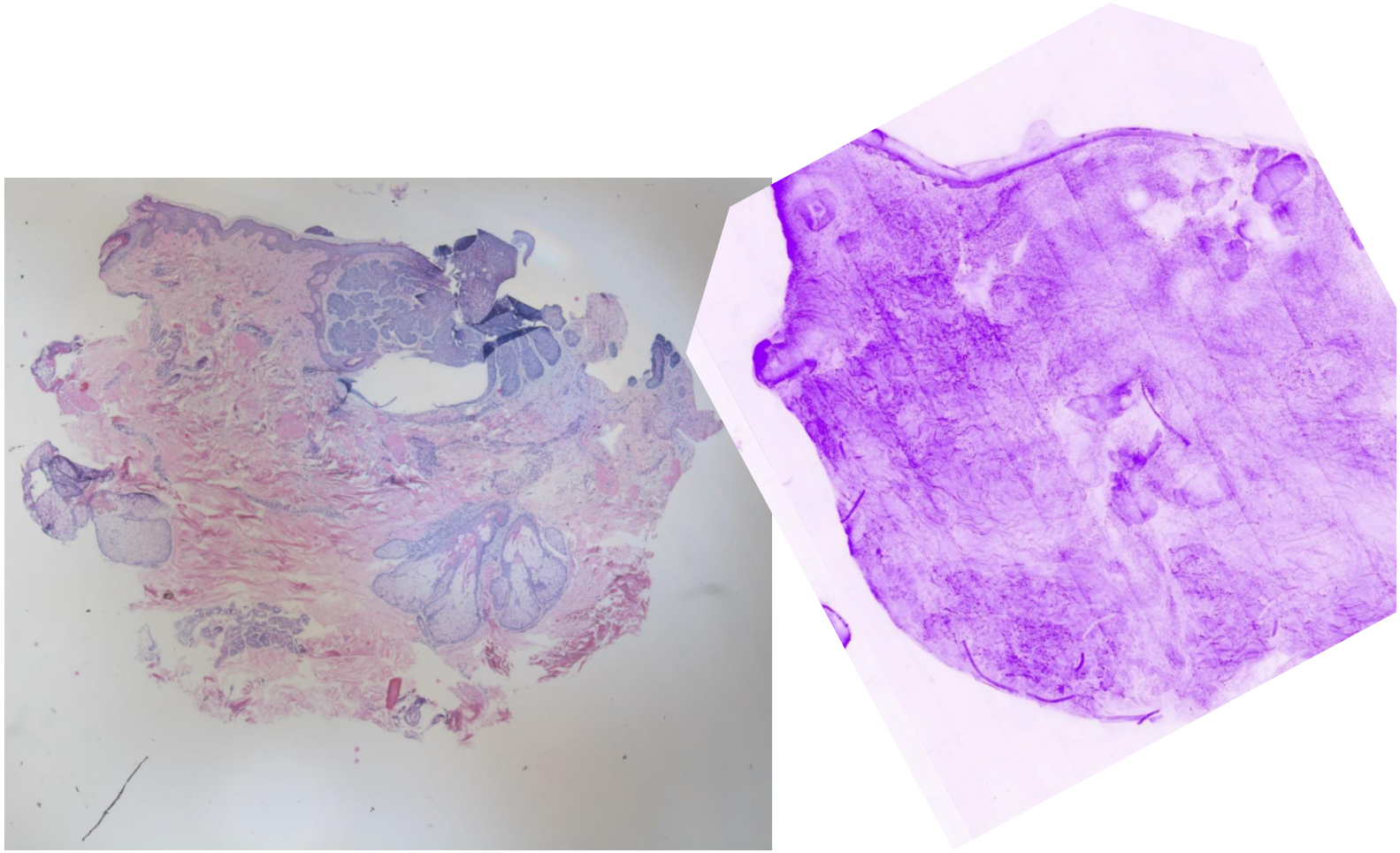

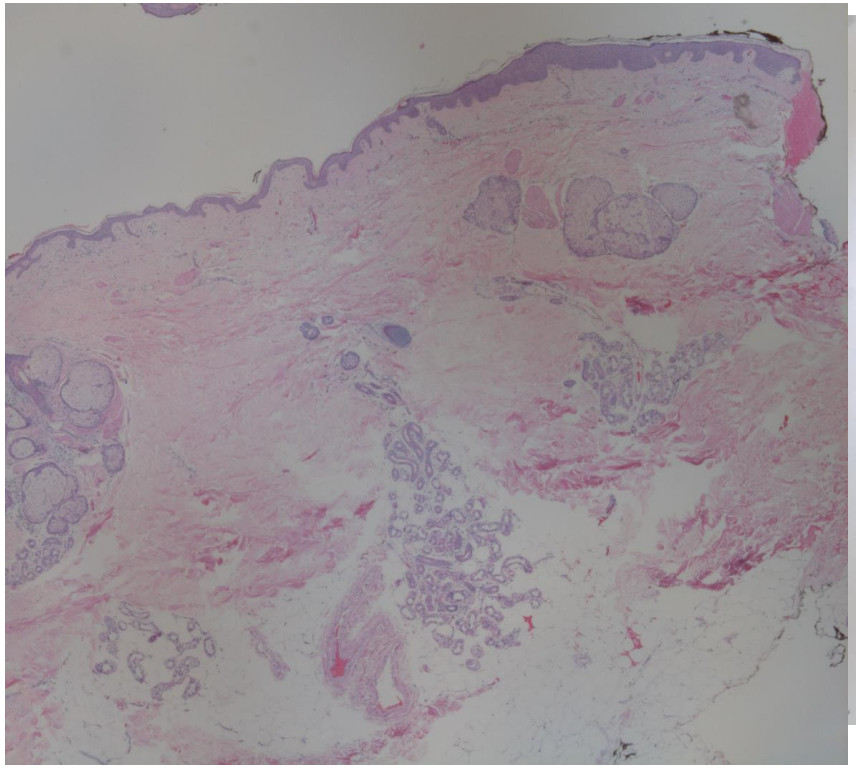

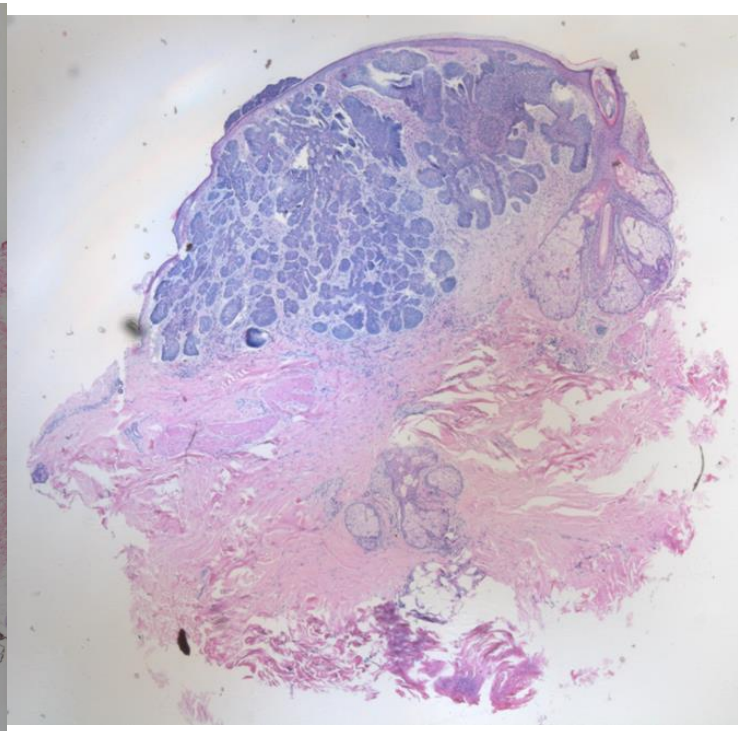

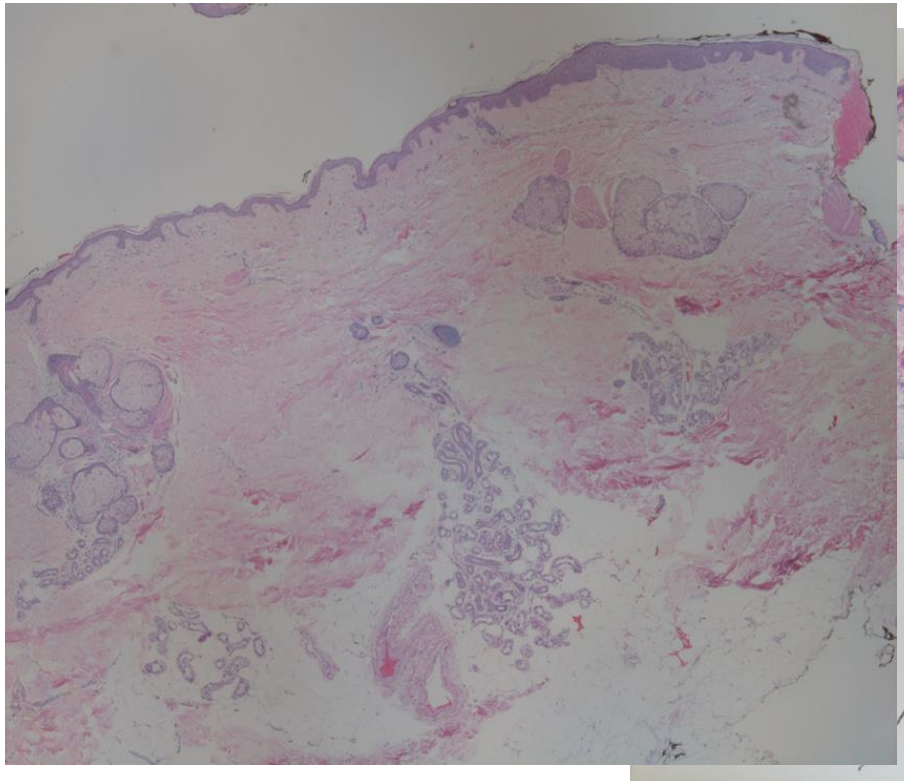

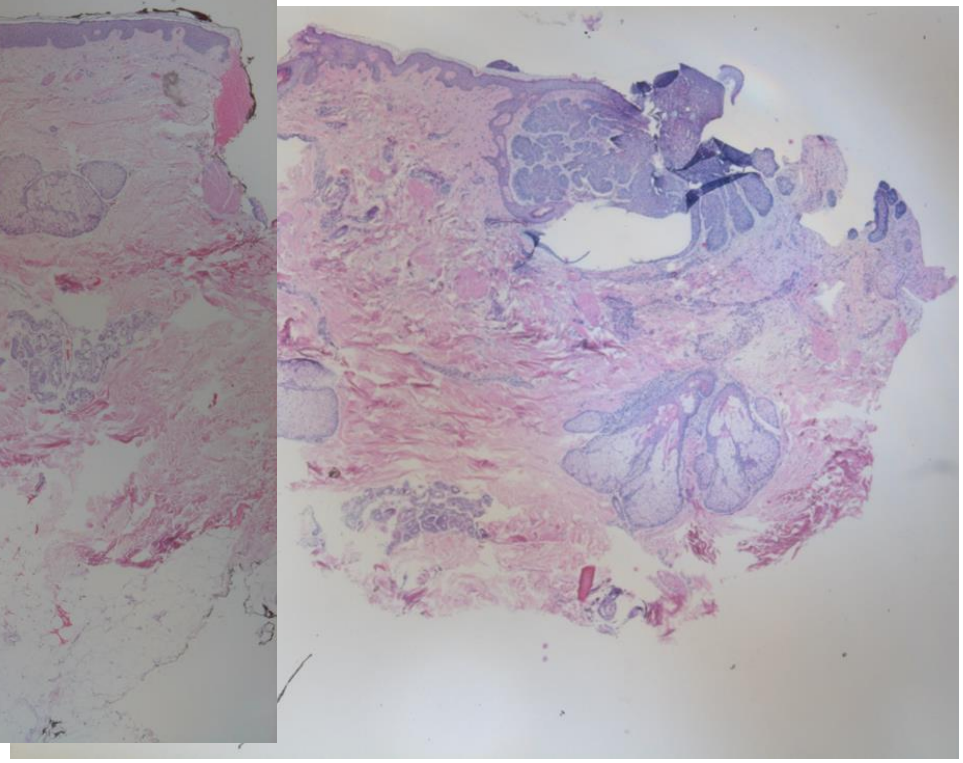

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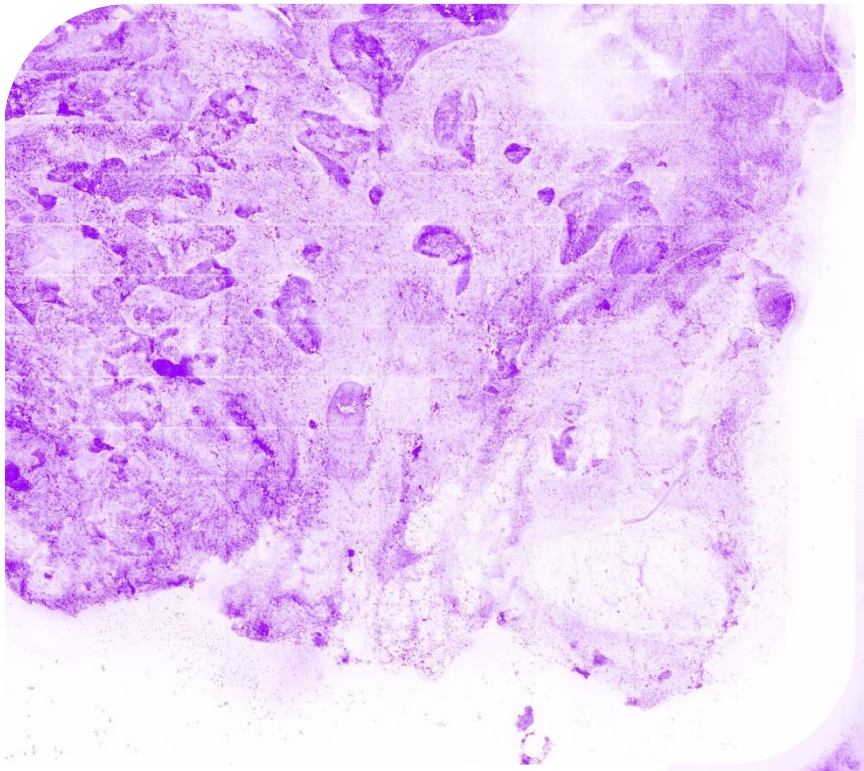

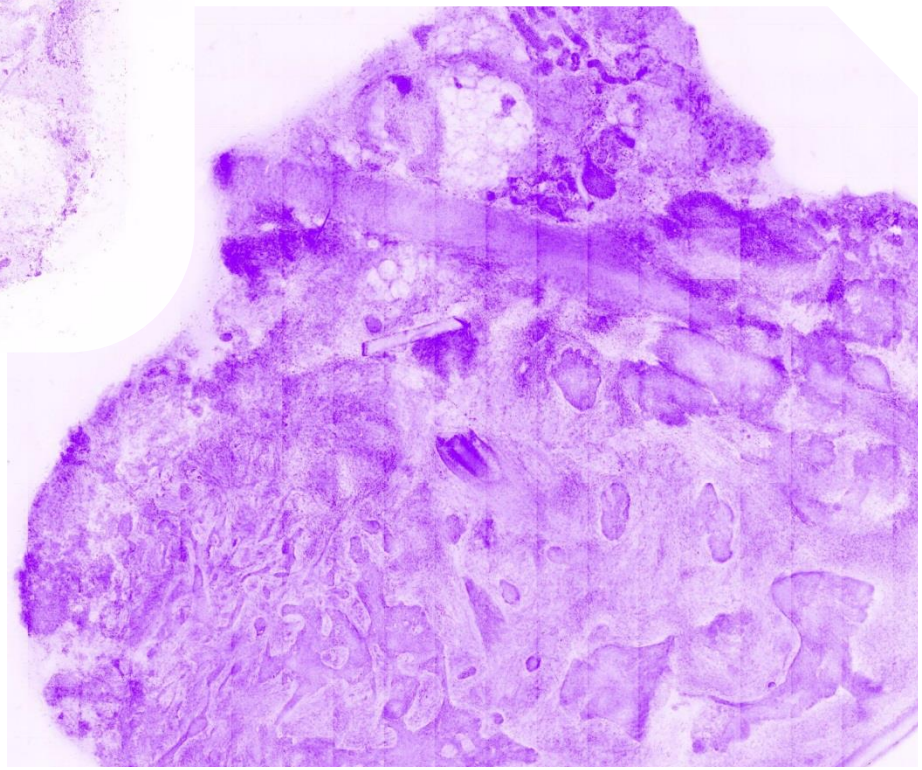

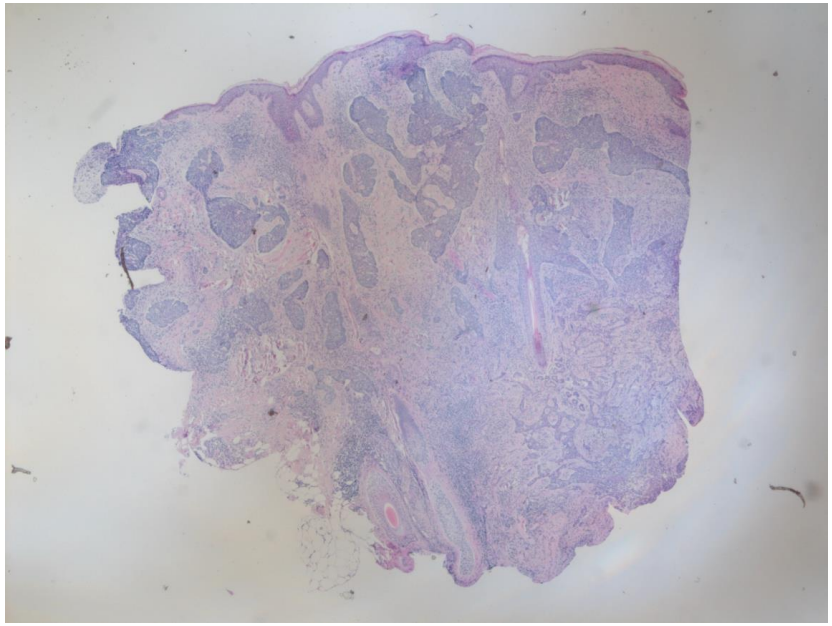

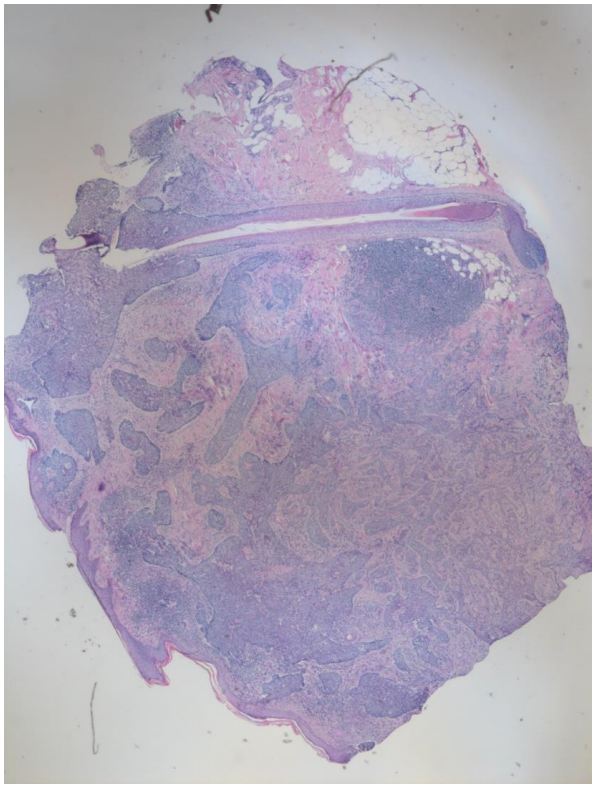

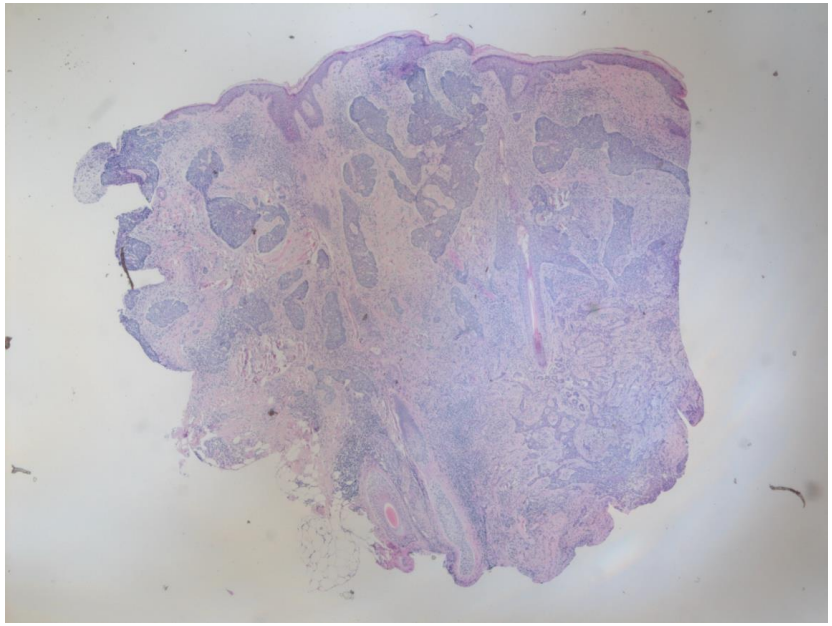

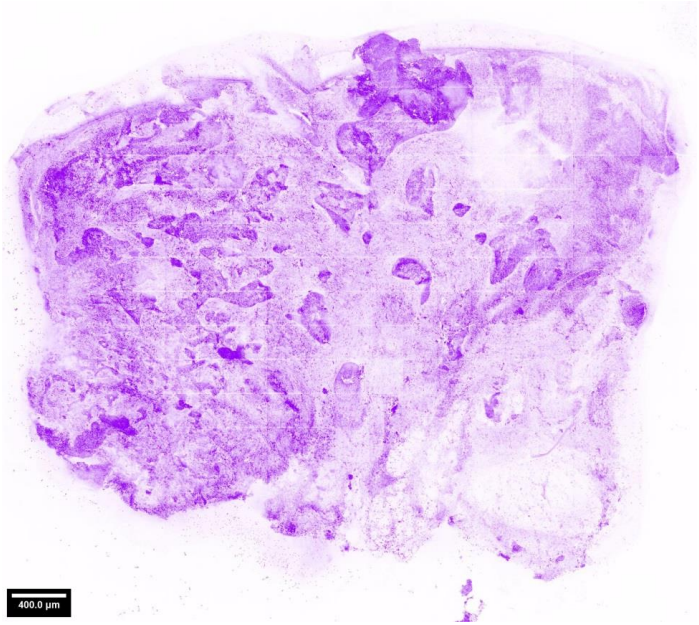
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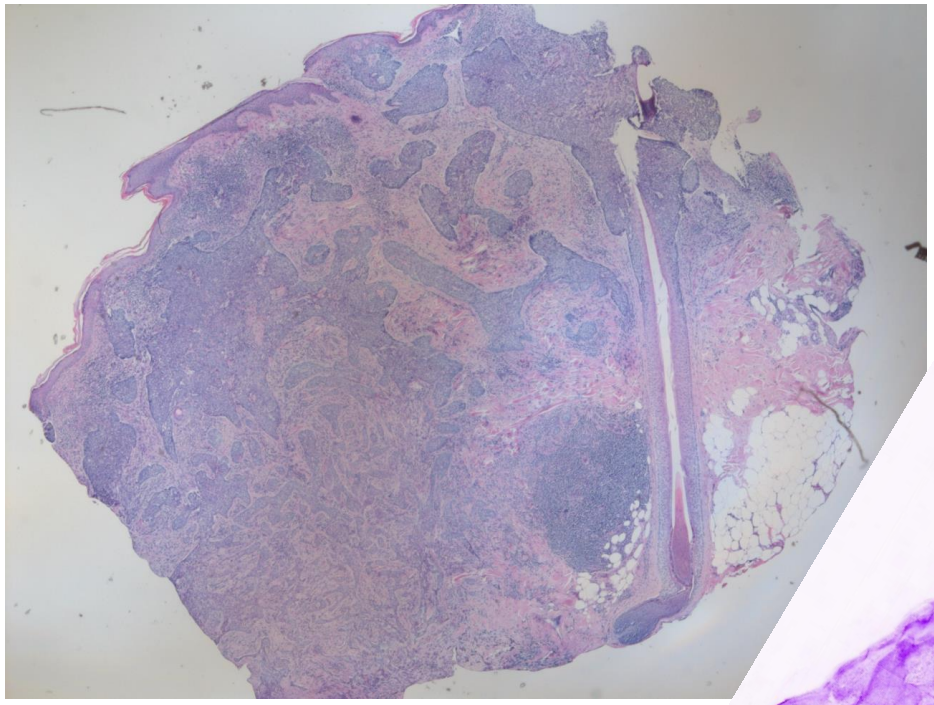

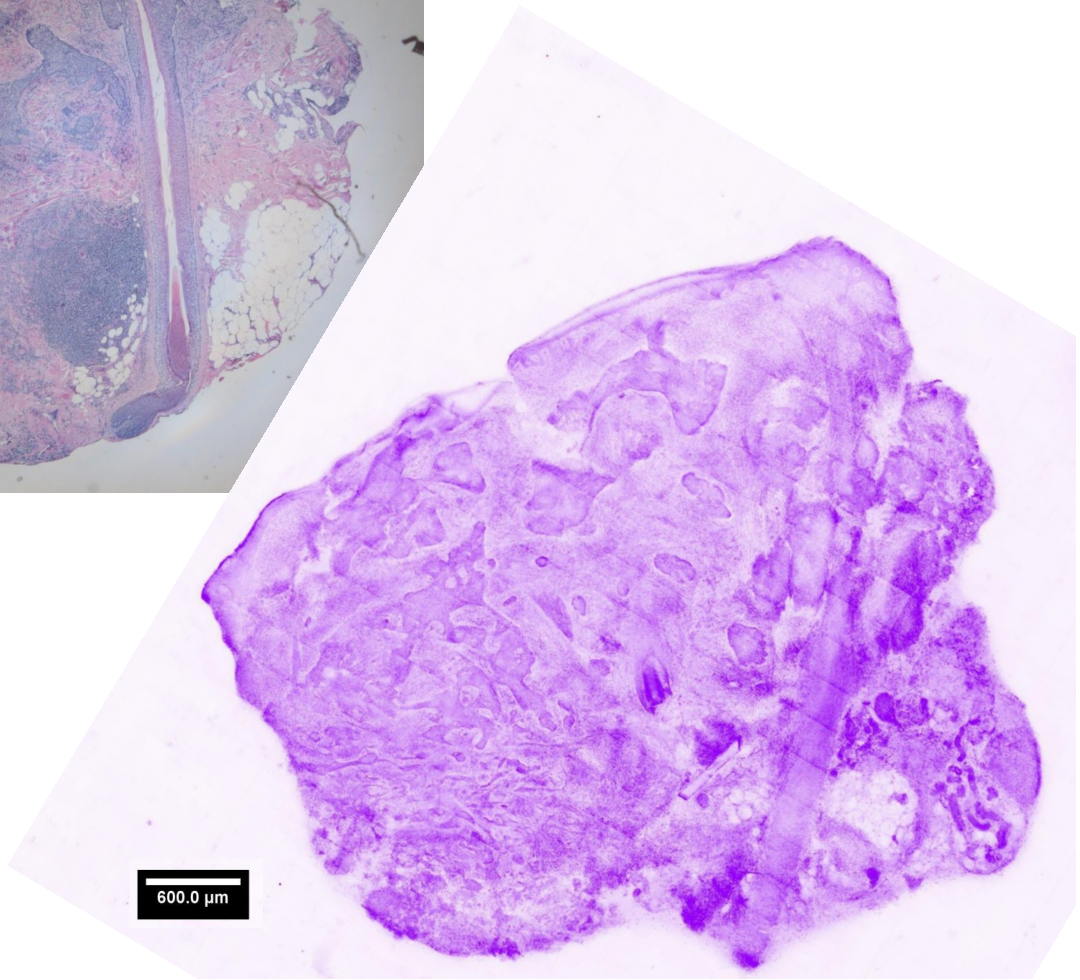
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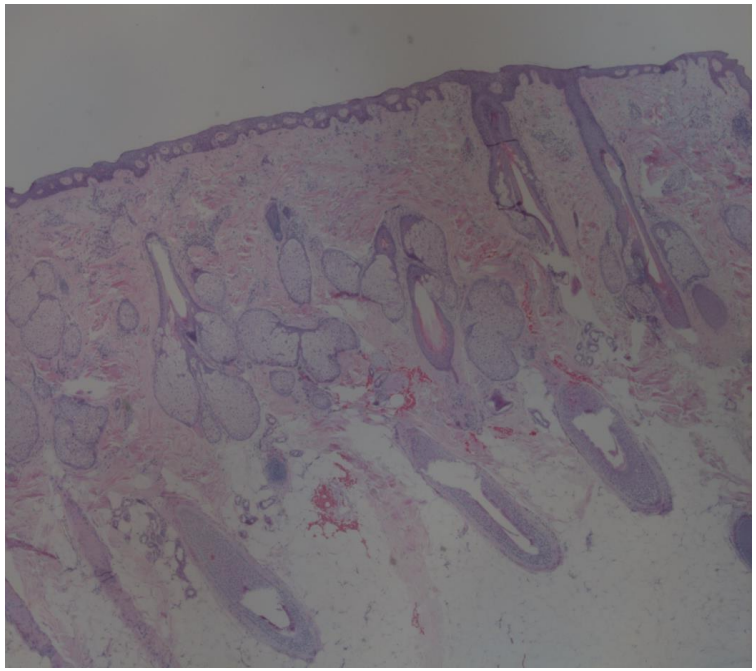
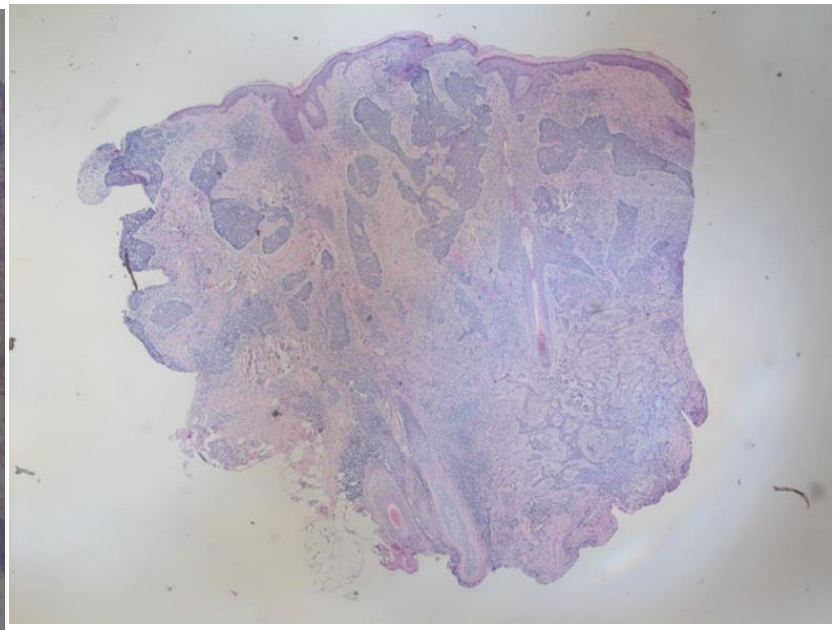
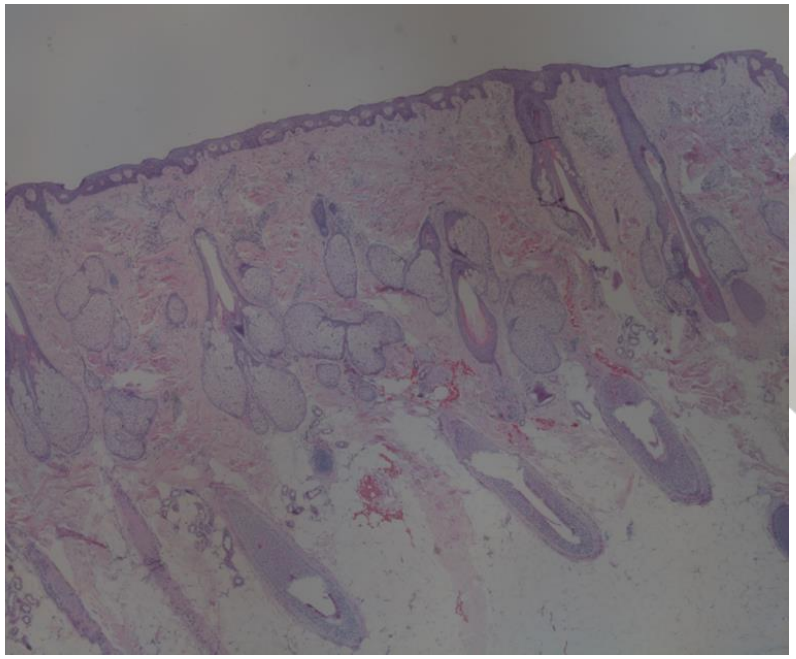
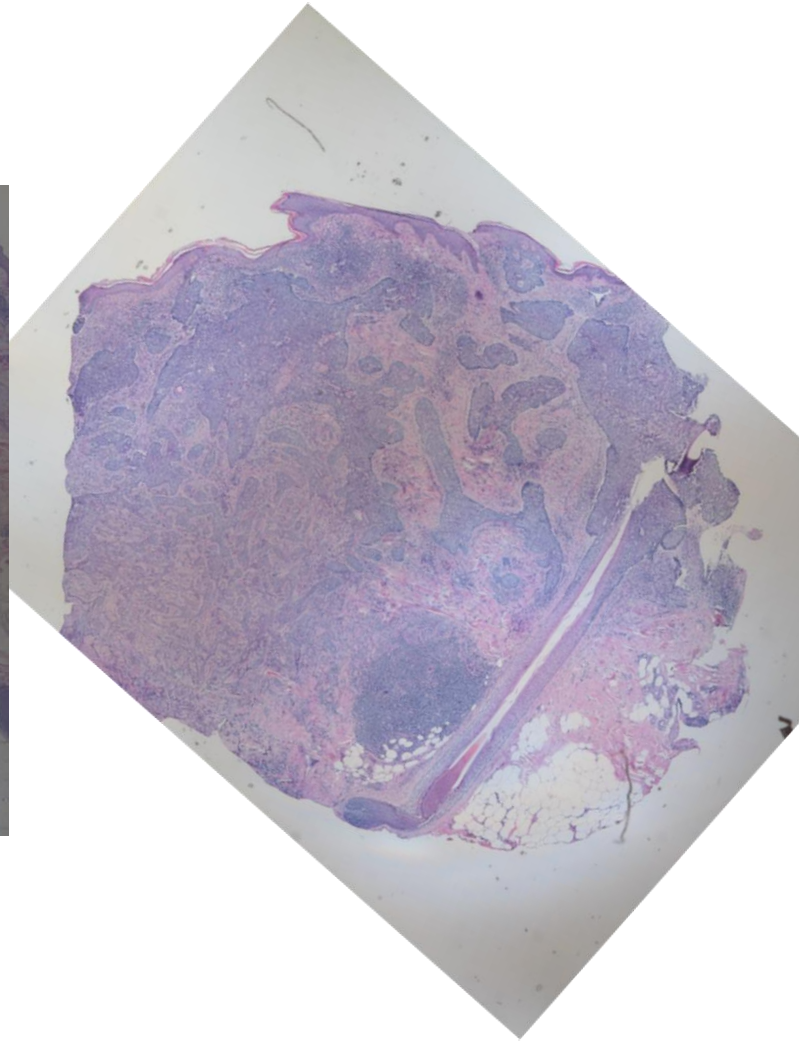
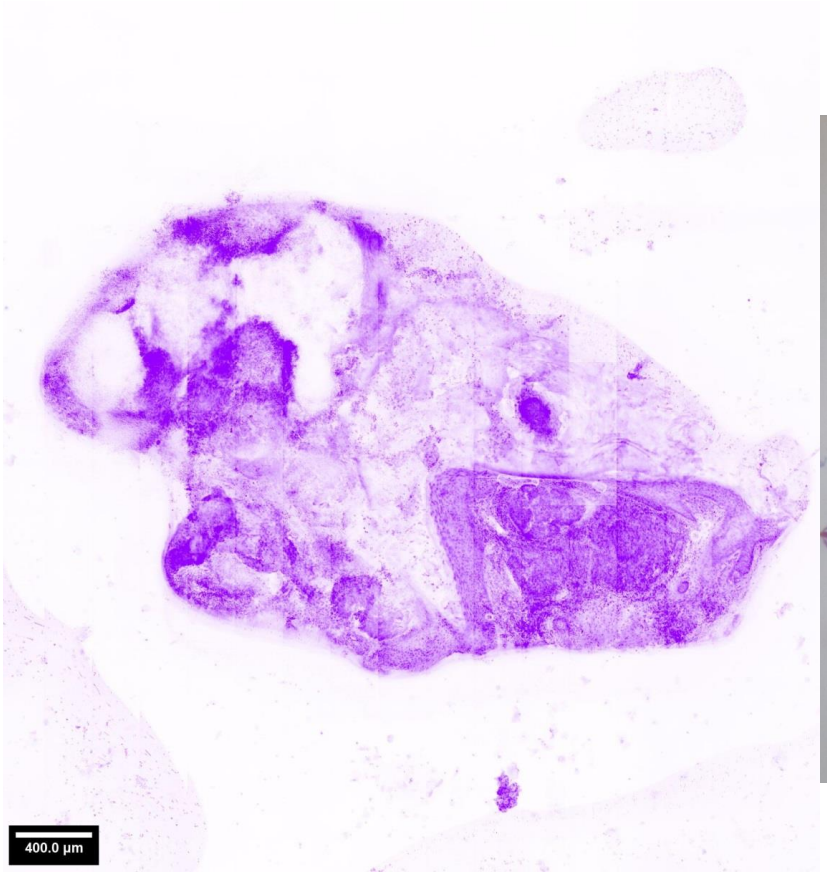


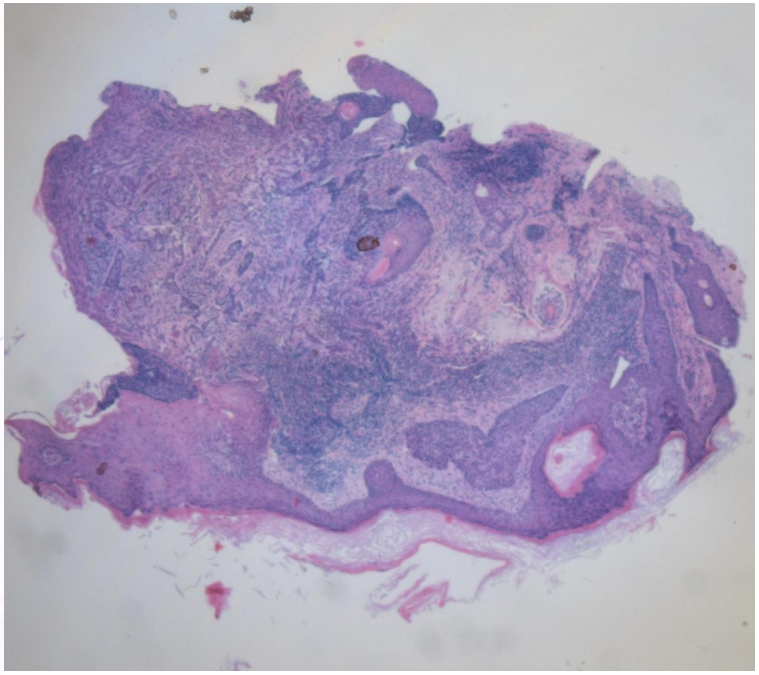


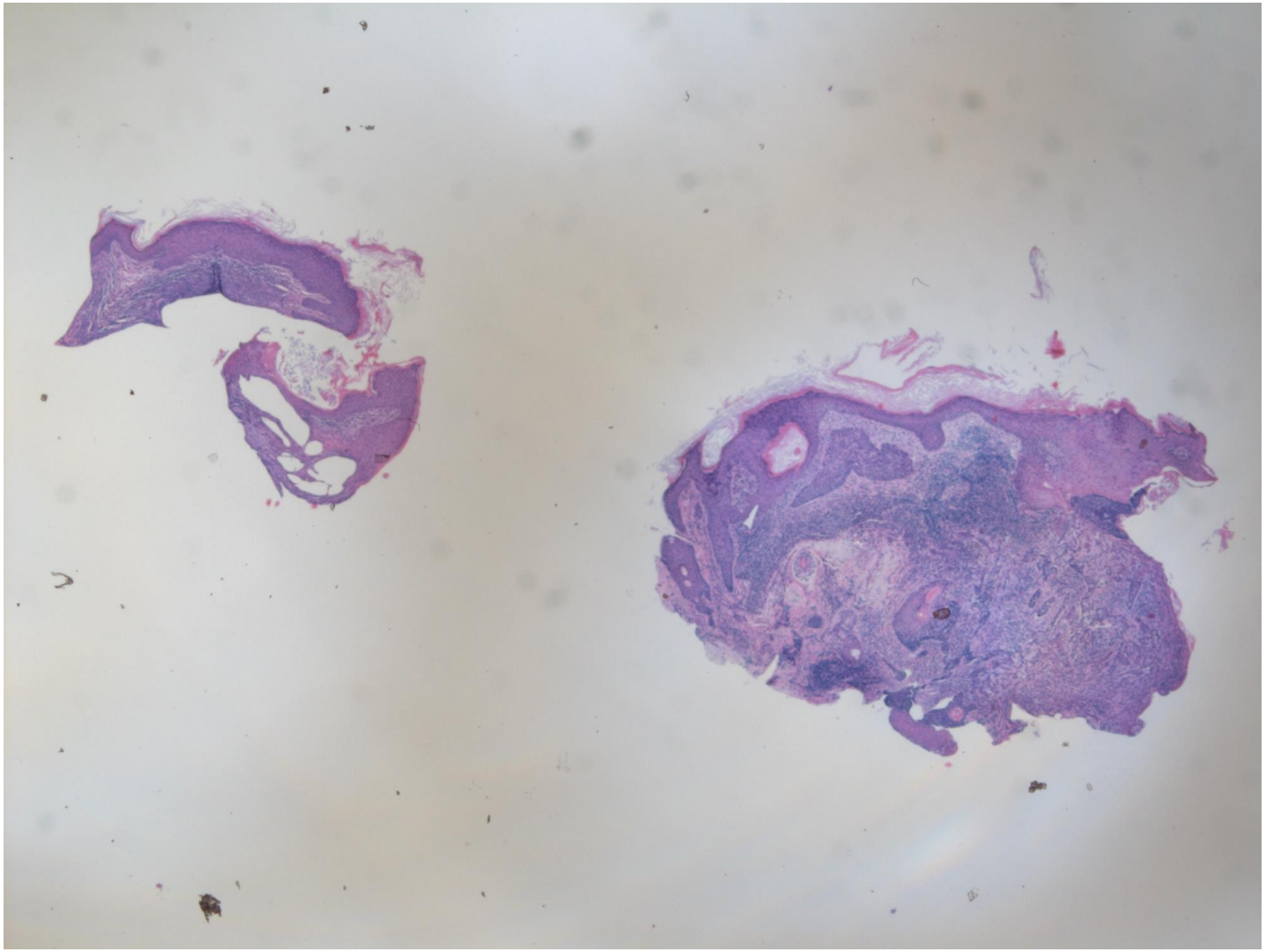


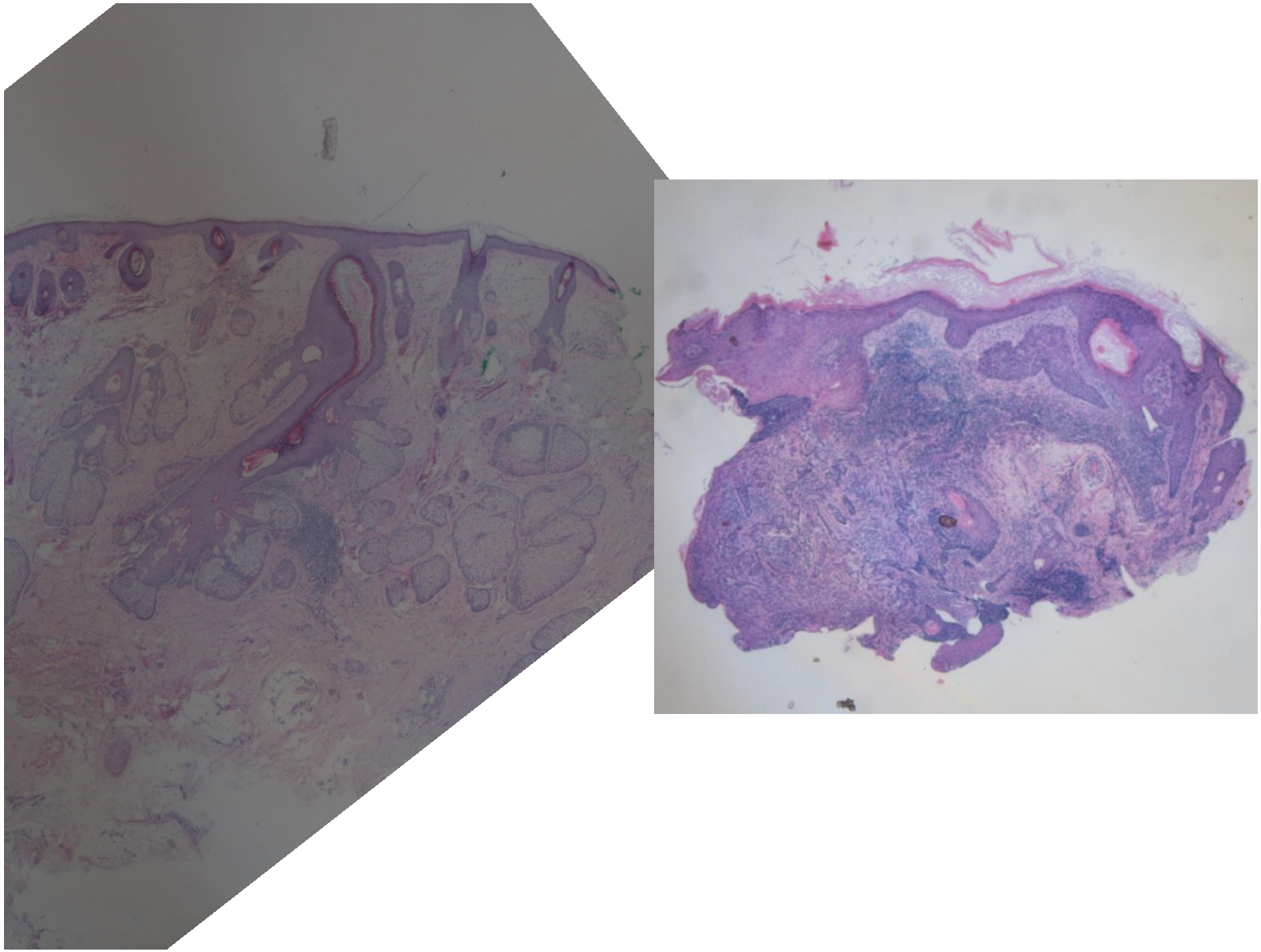


NM









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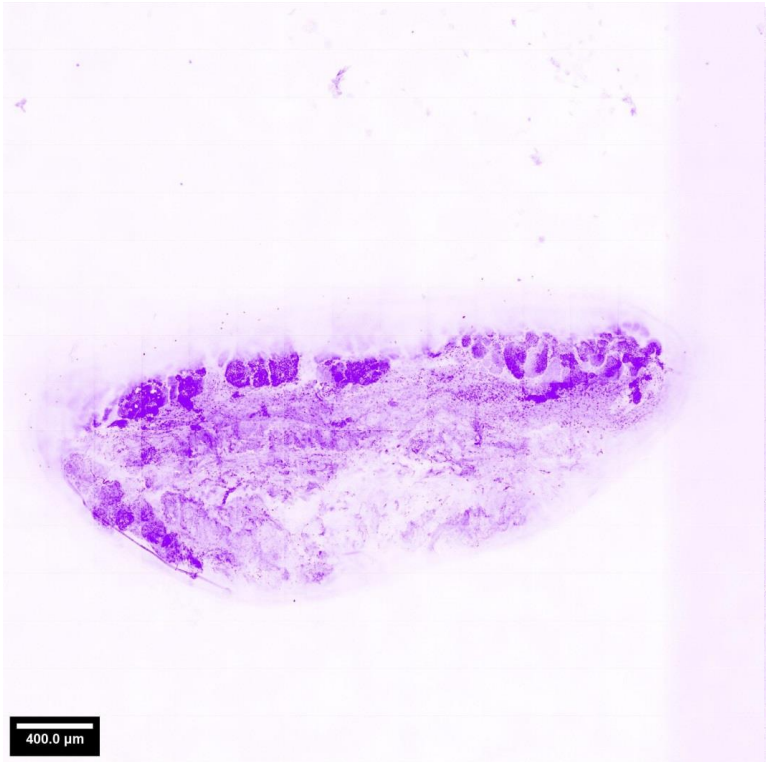

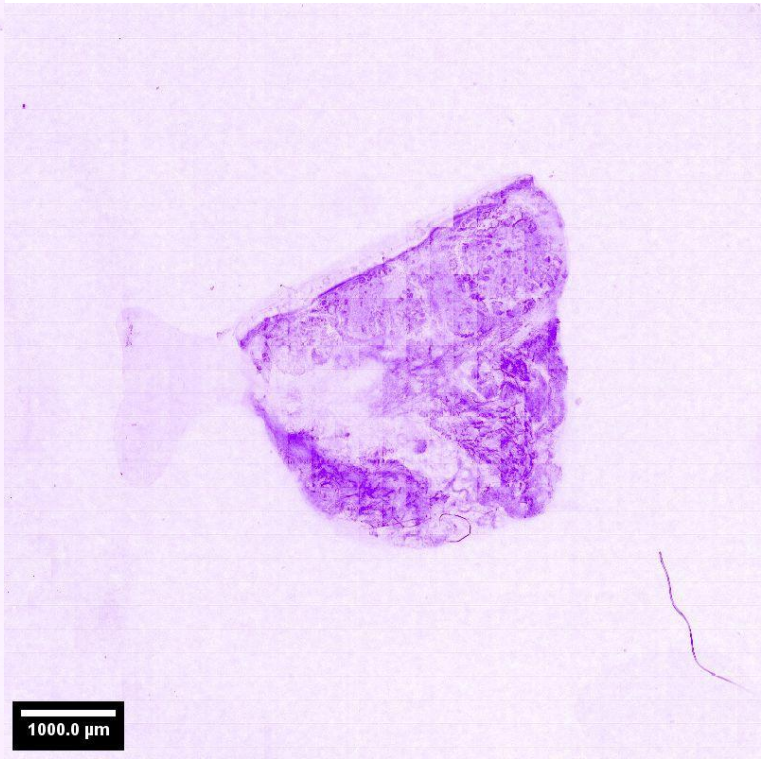

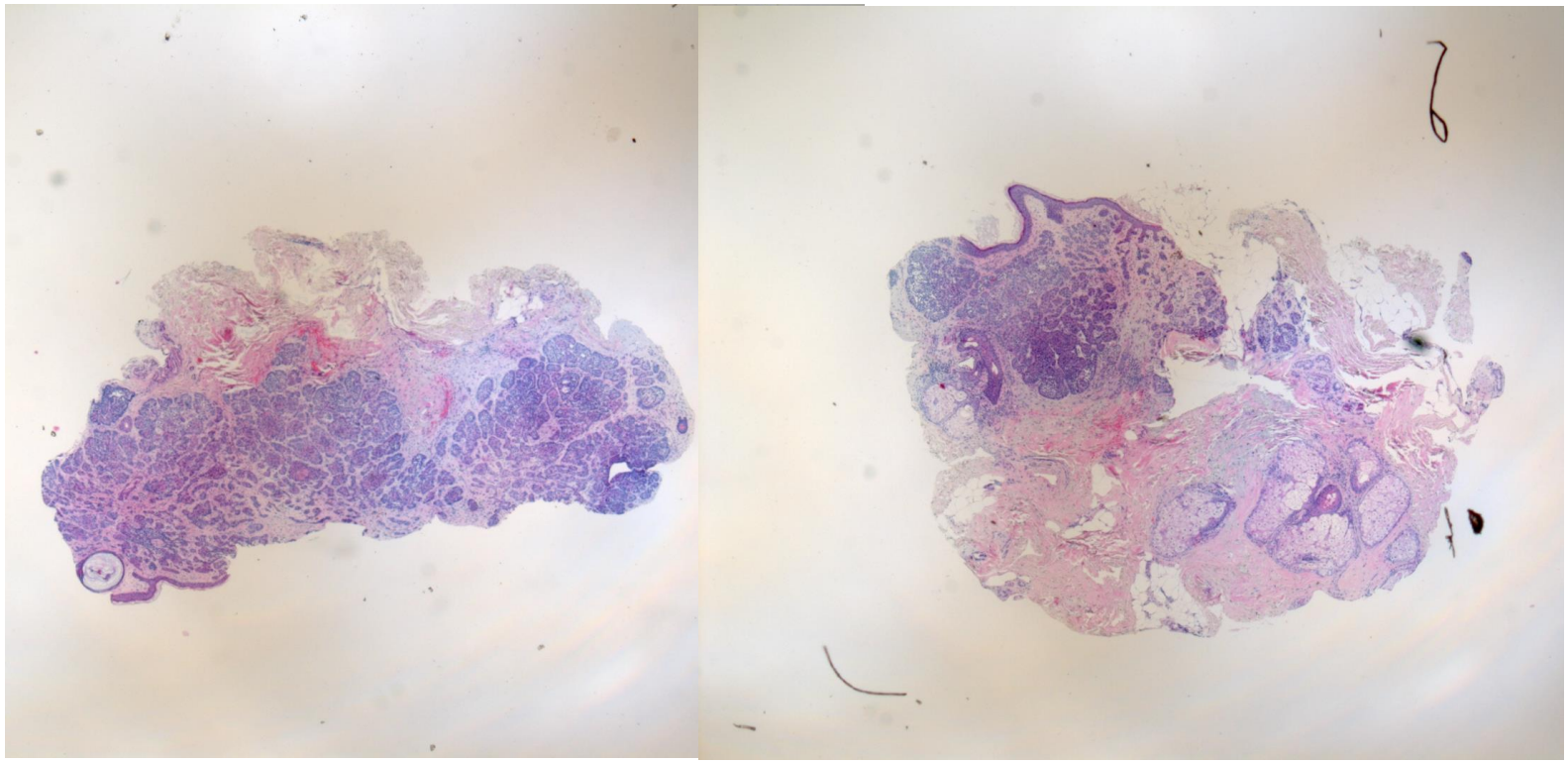

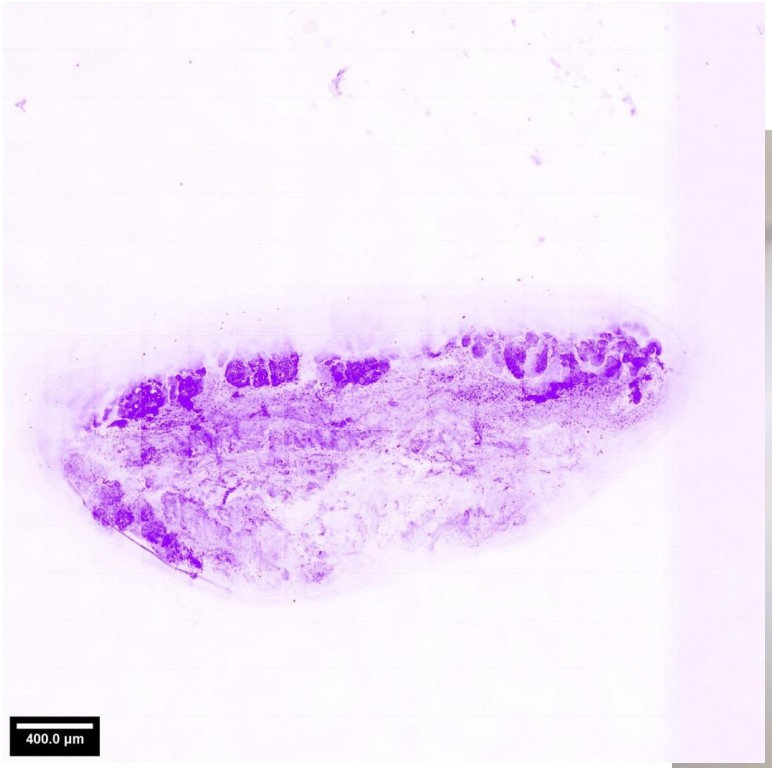
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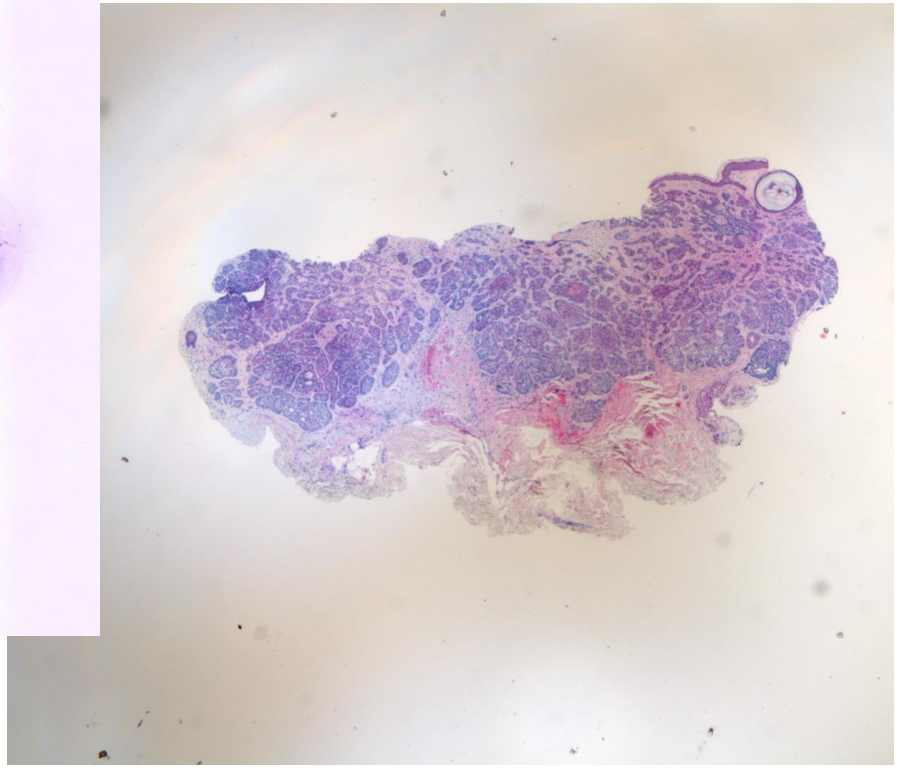

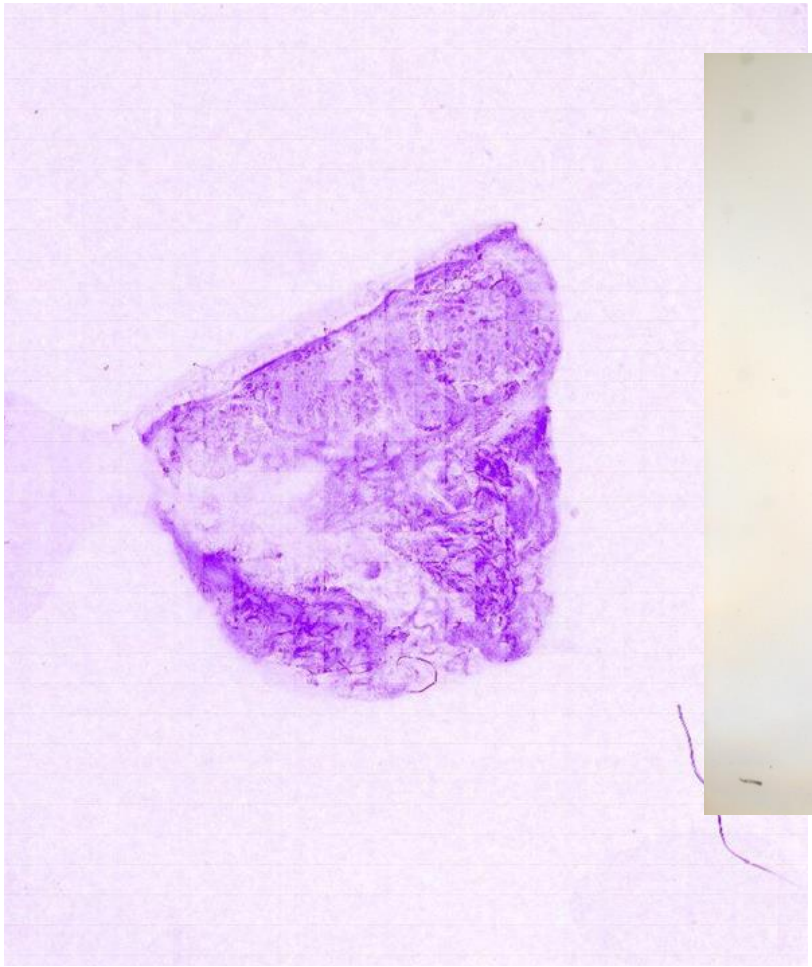

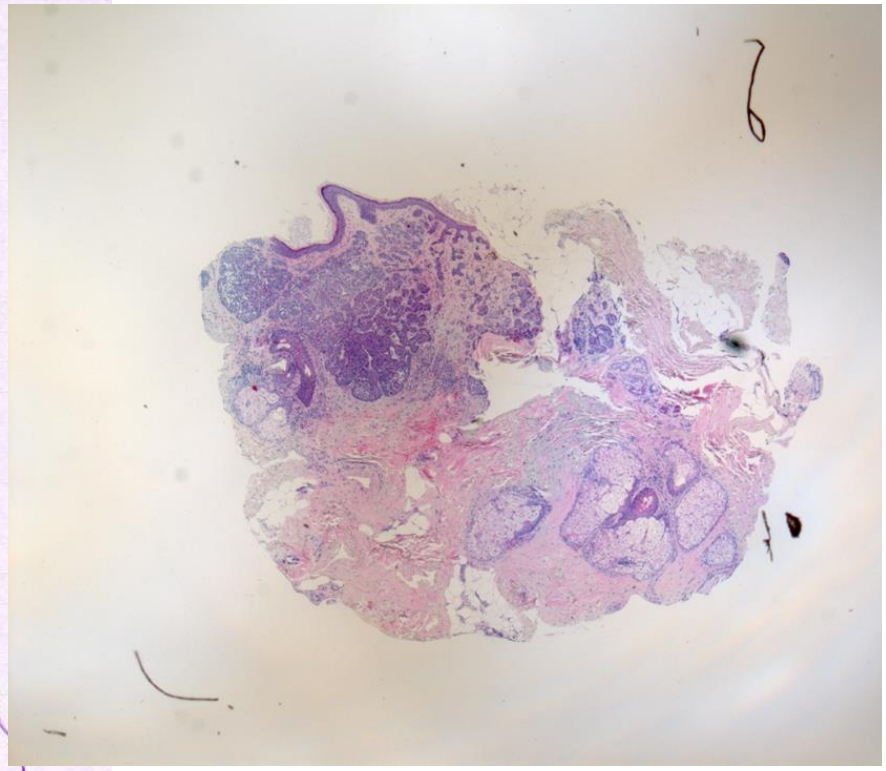

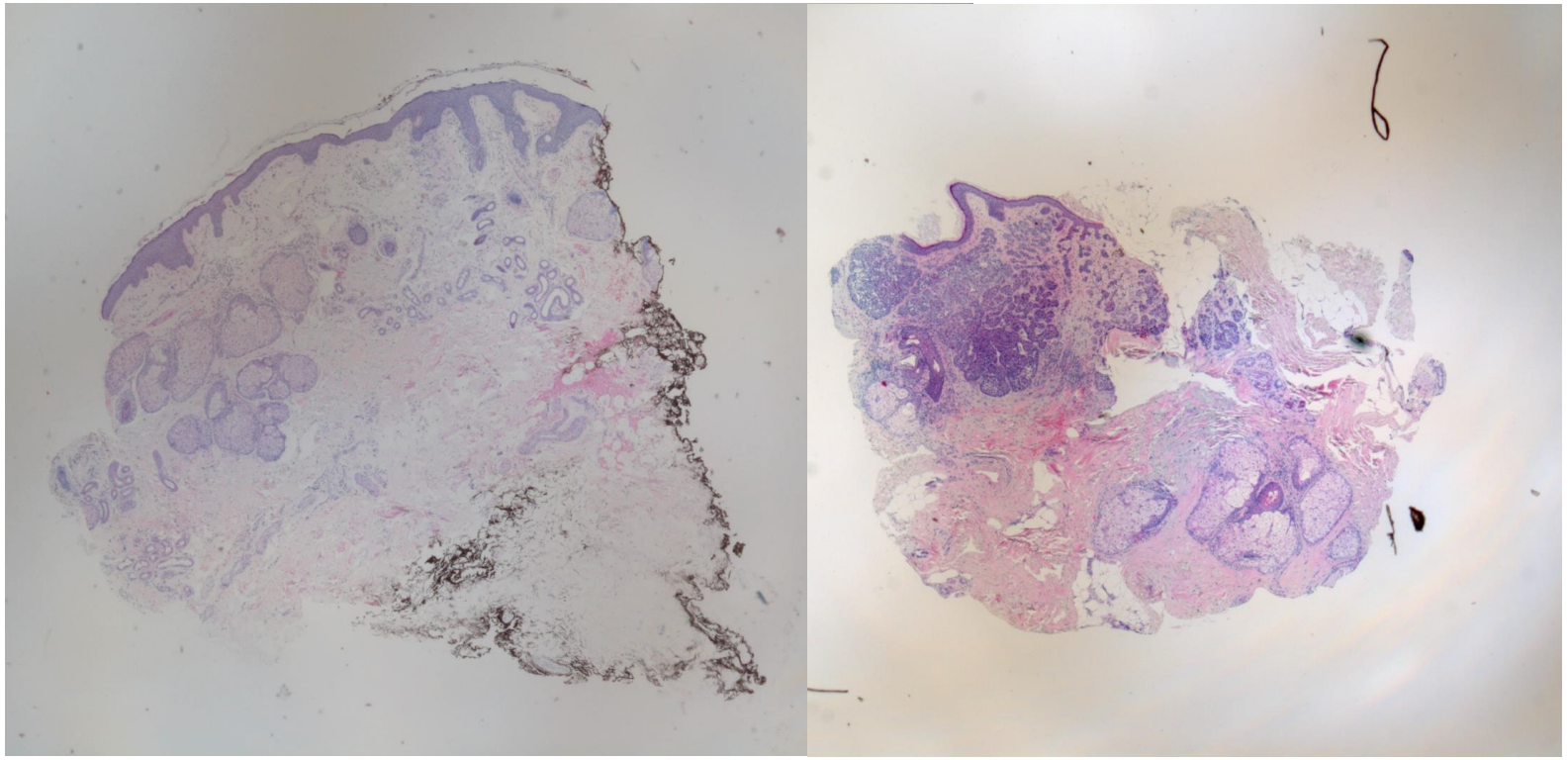

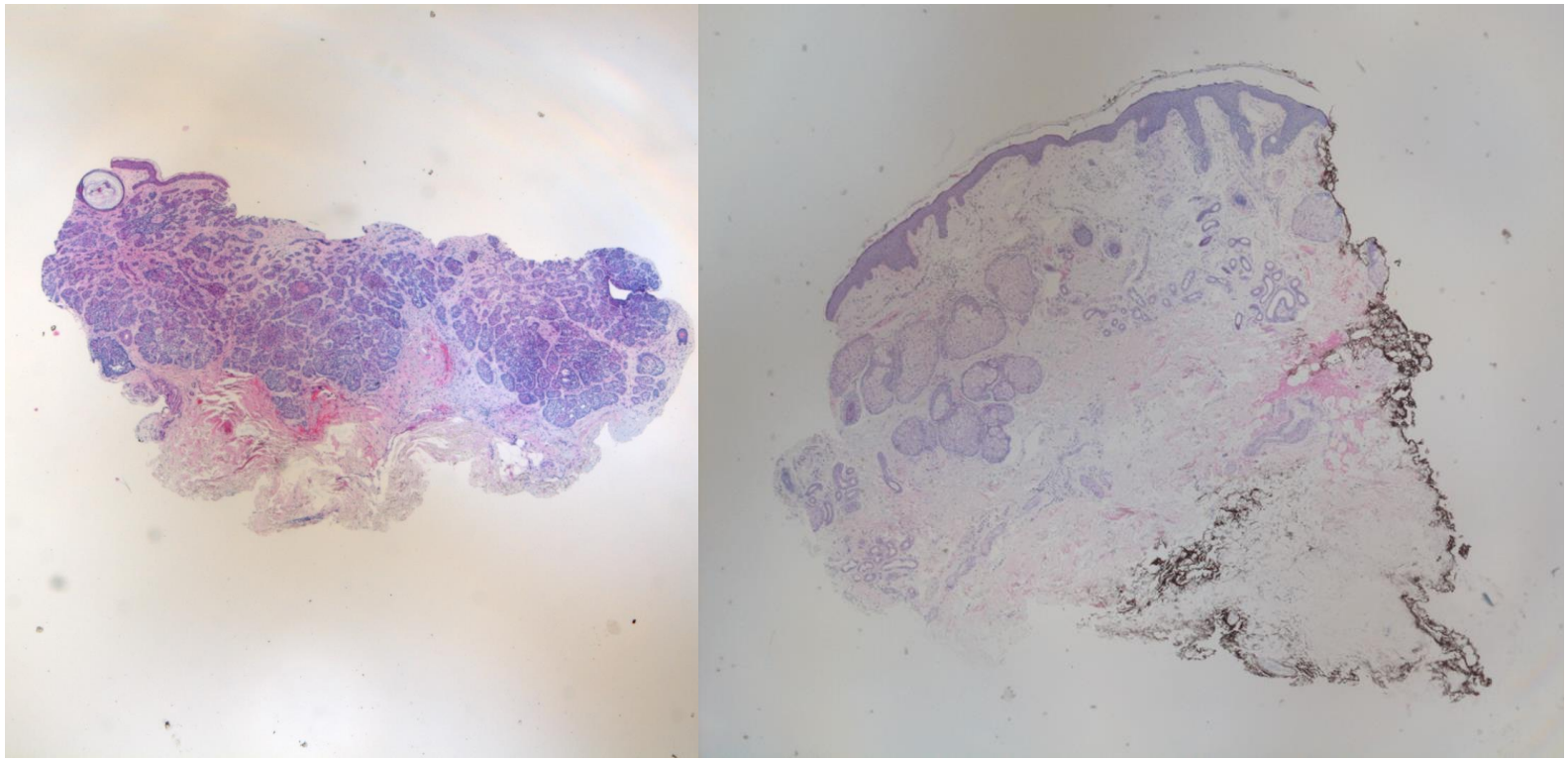

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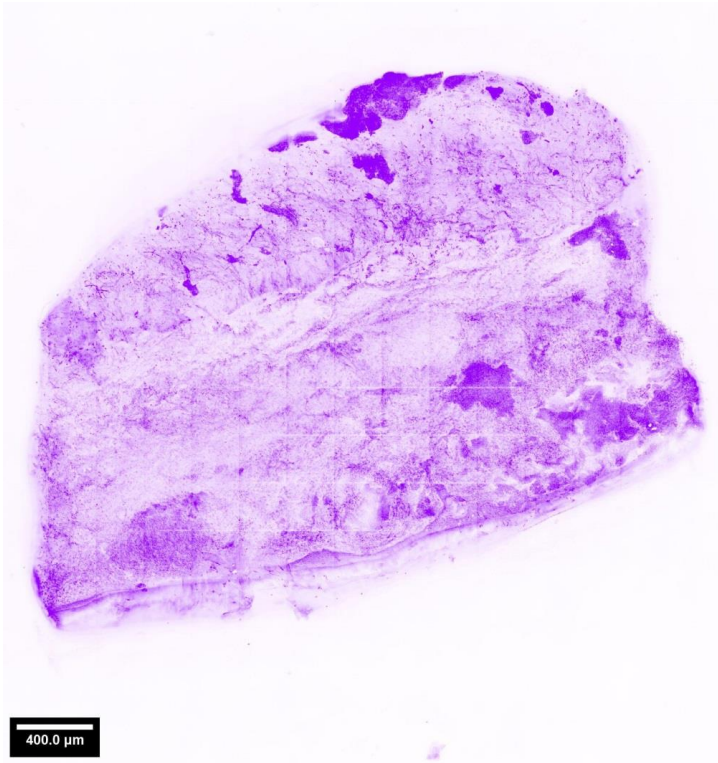

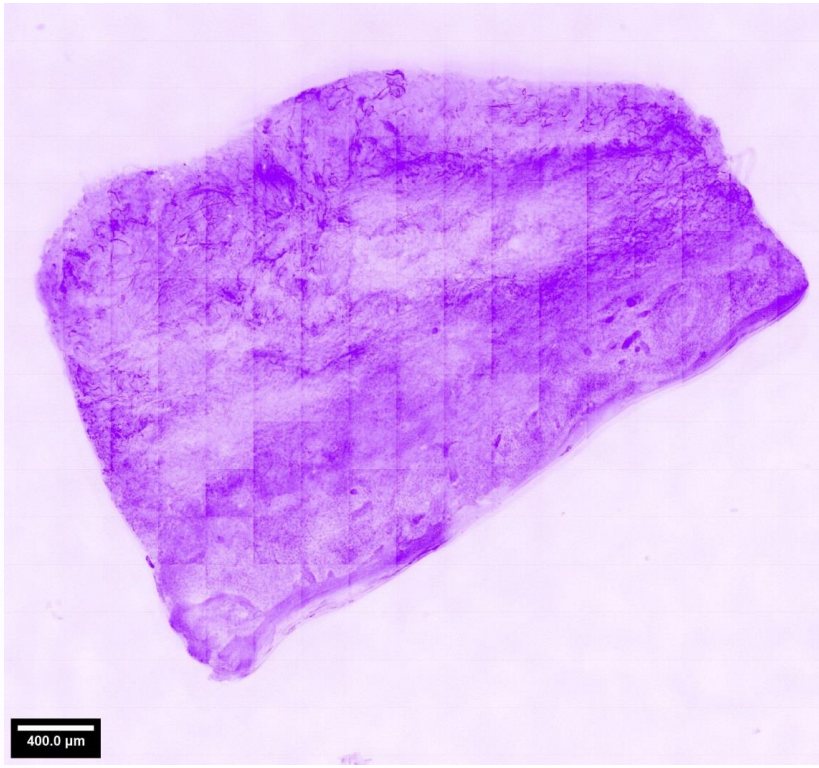

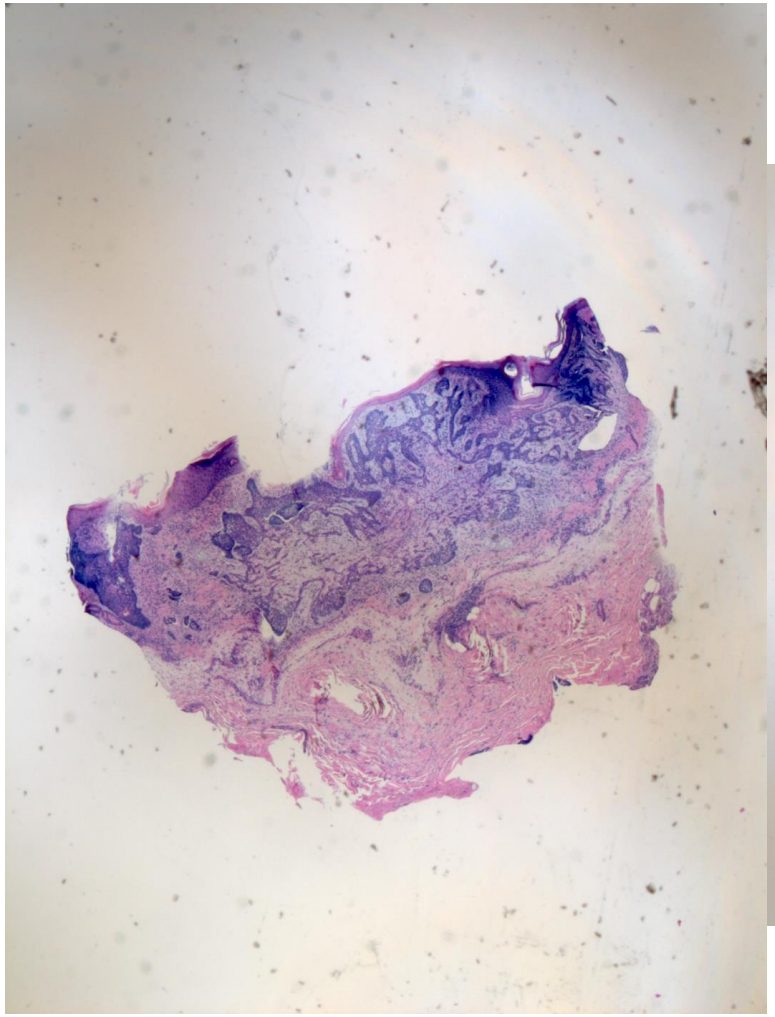

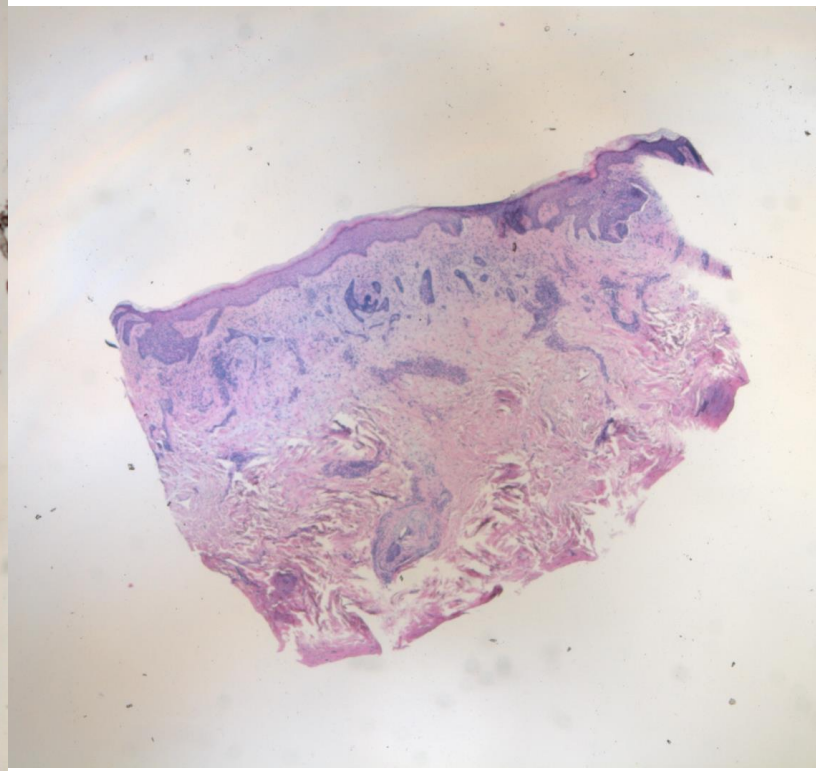

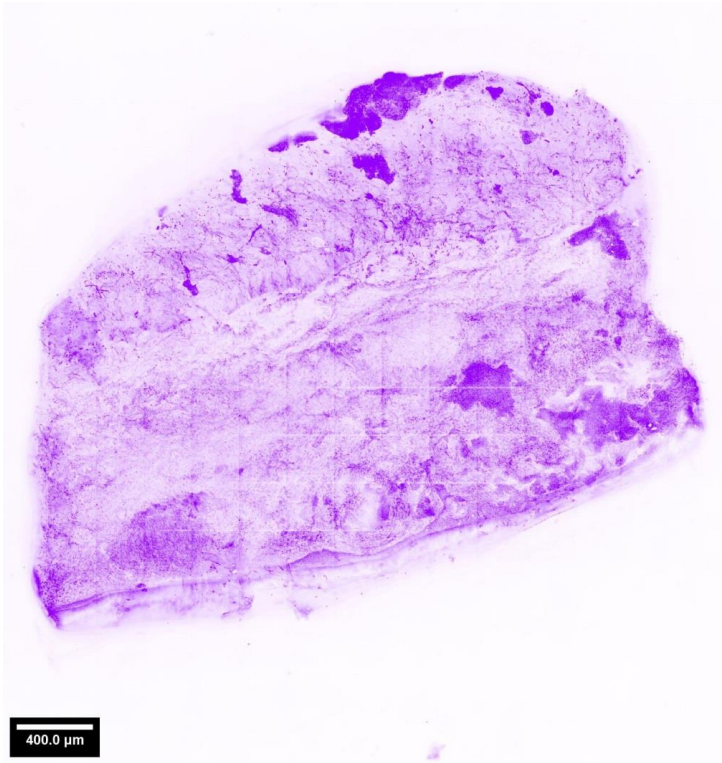
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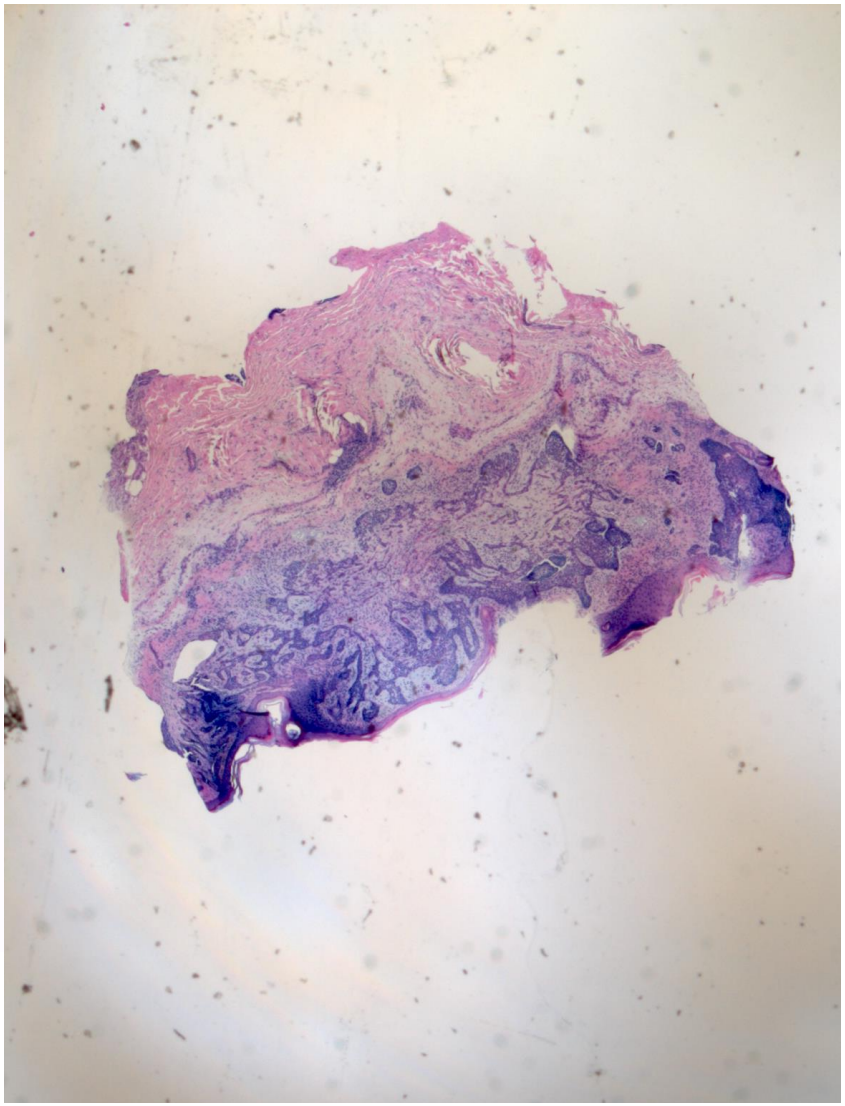

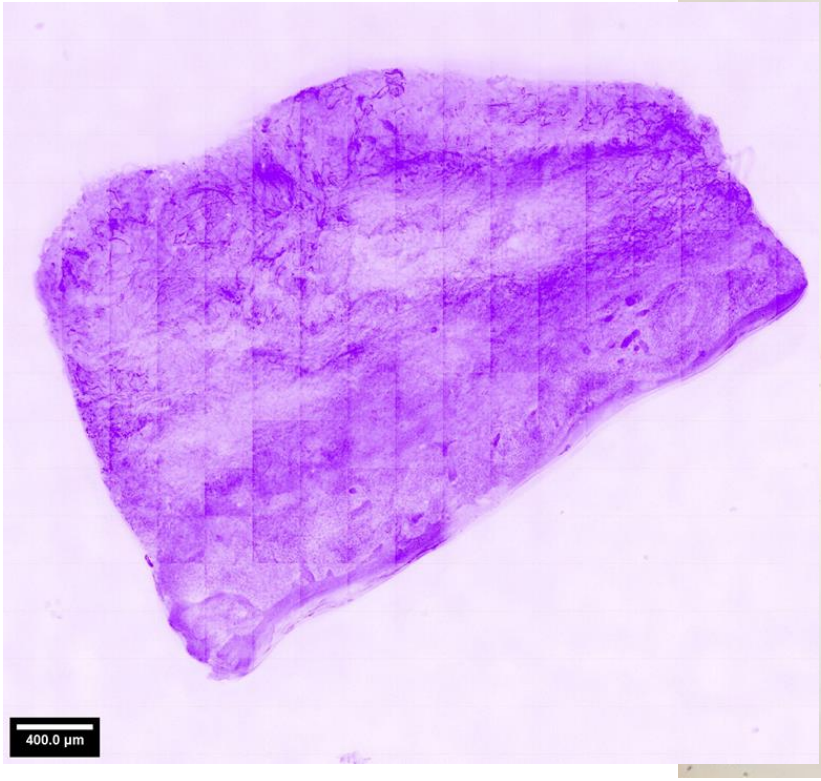
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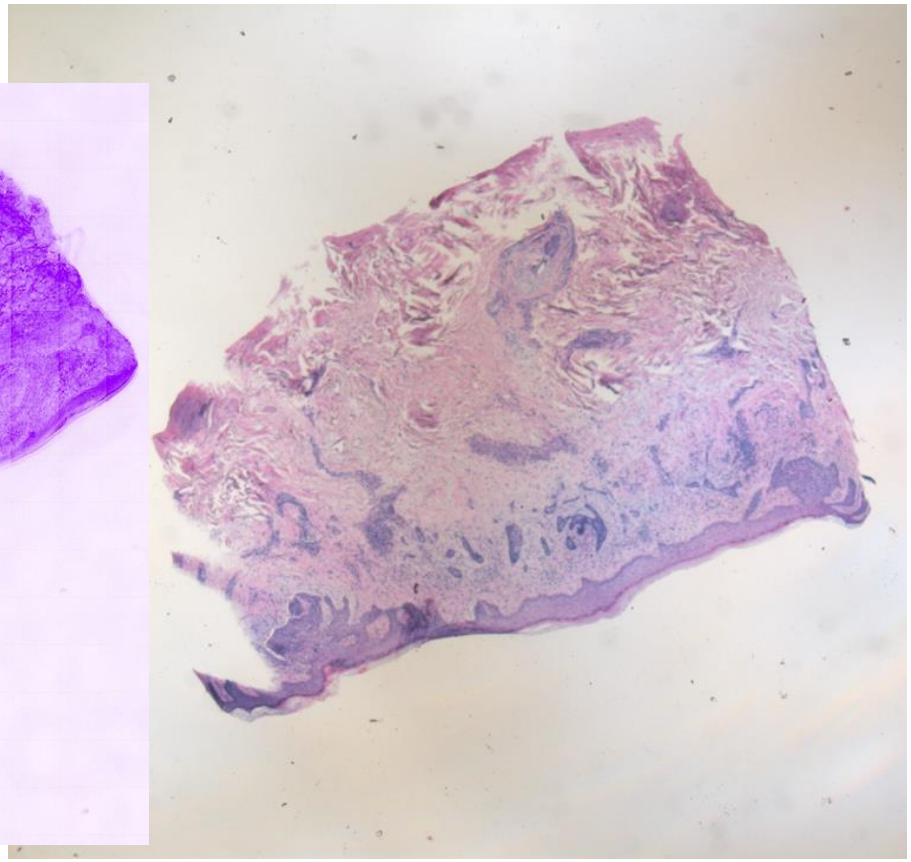

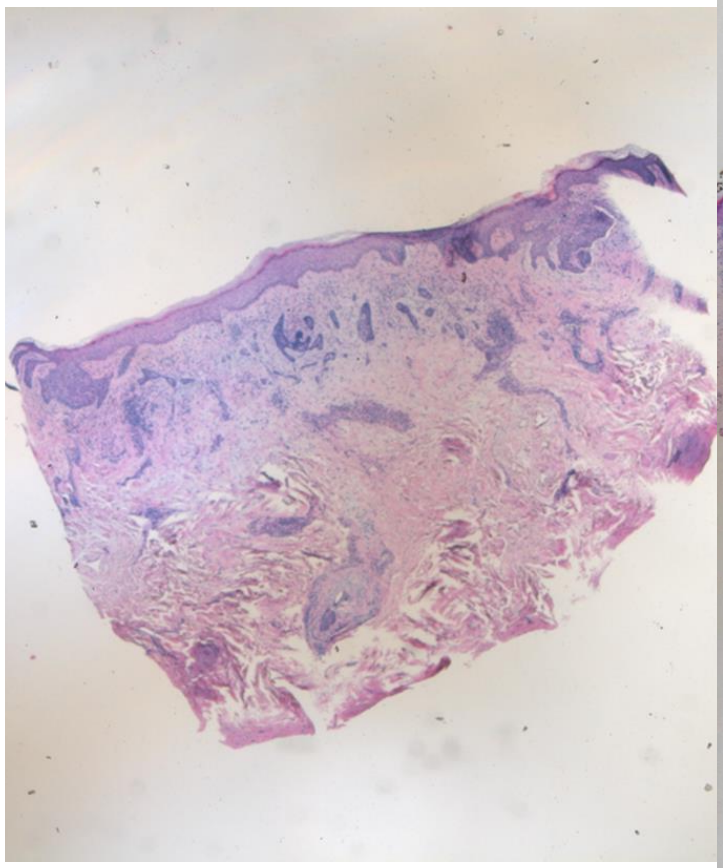

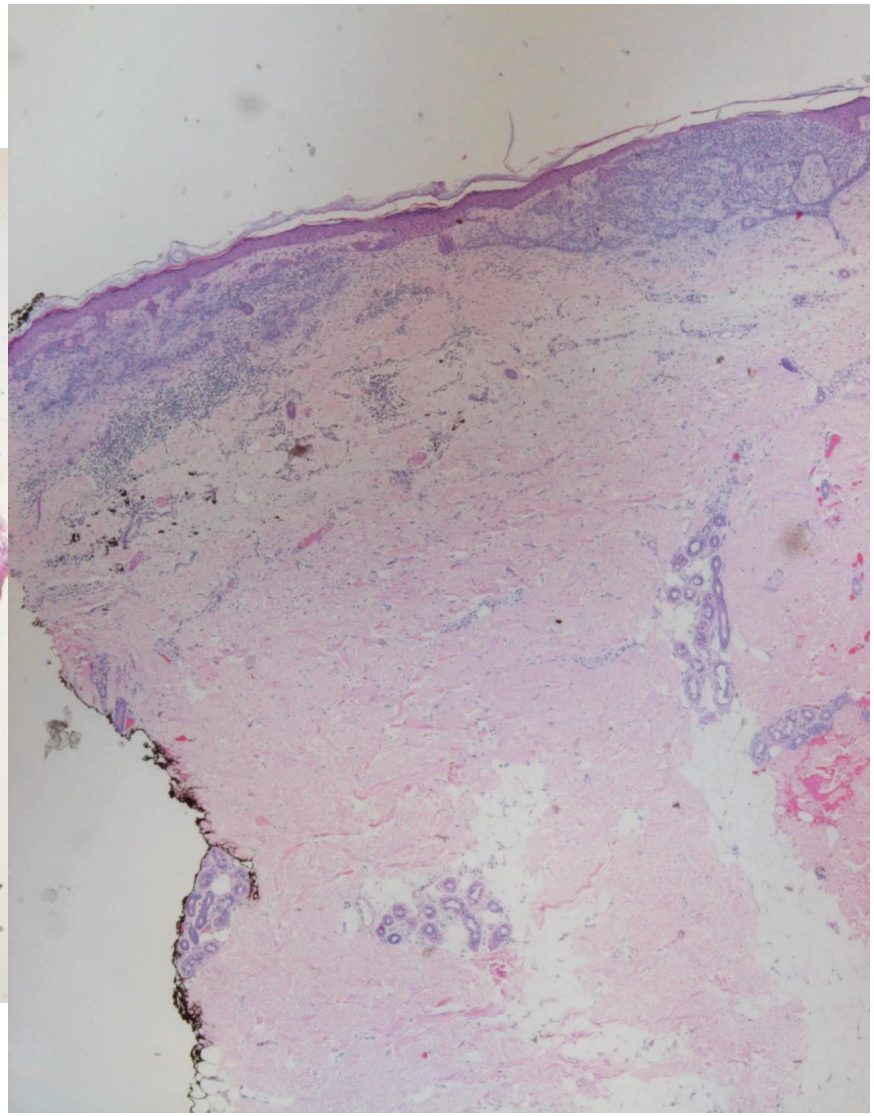

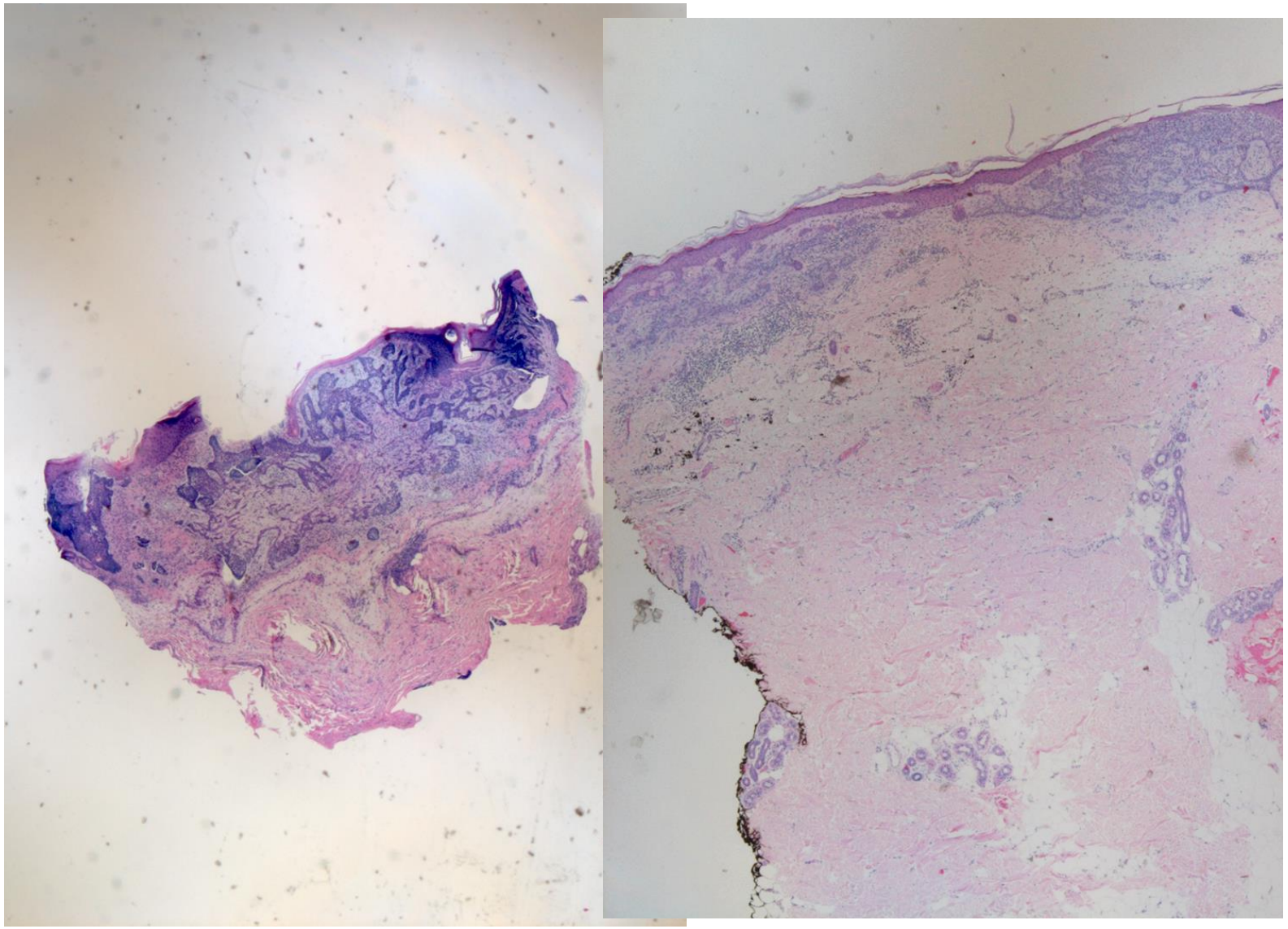

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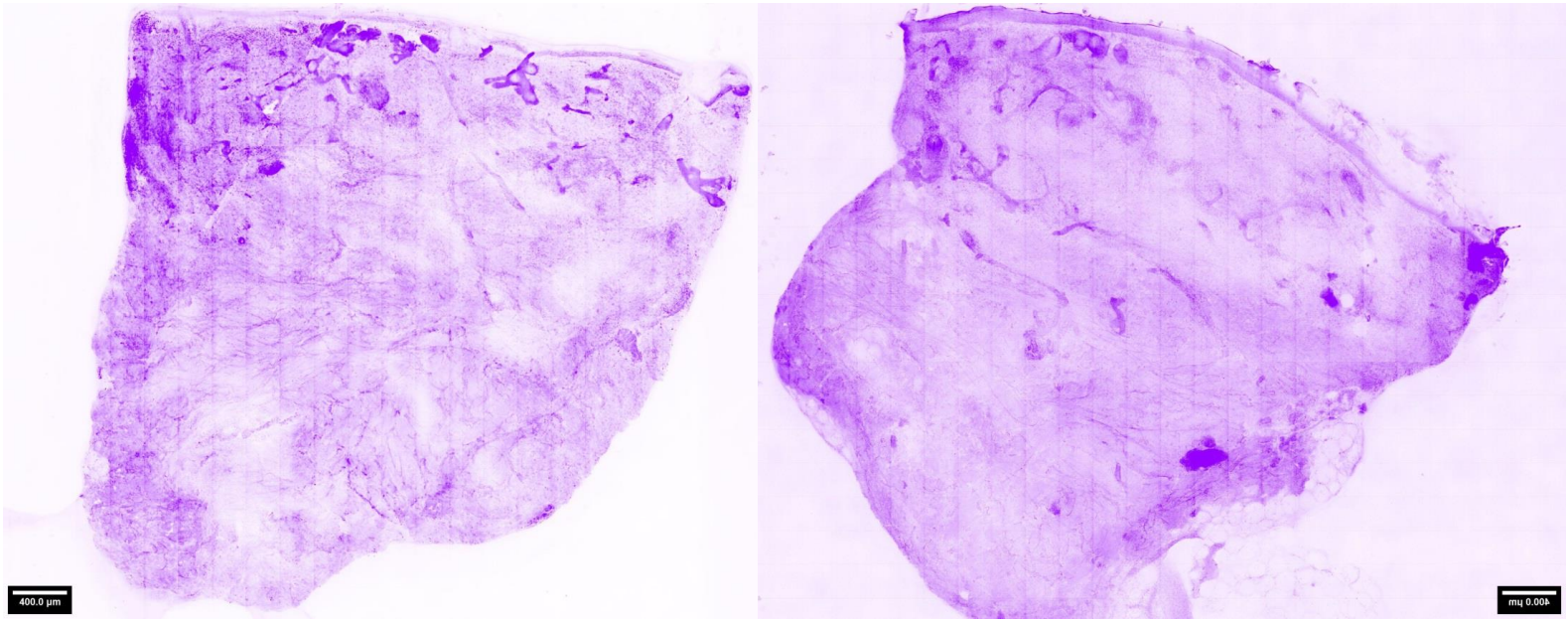

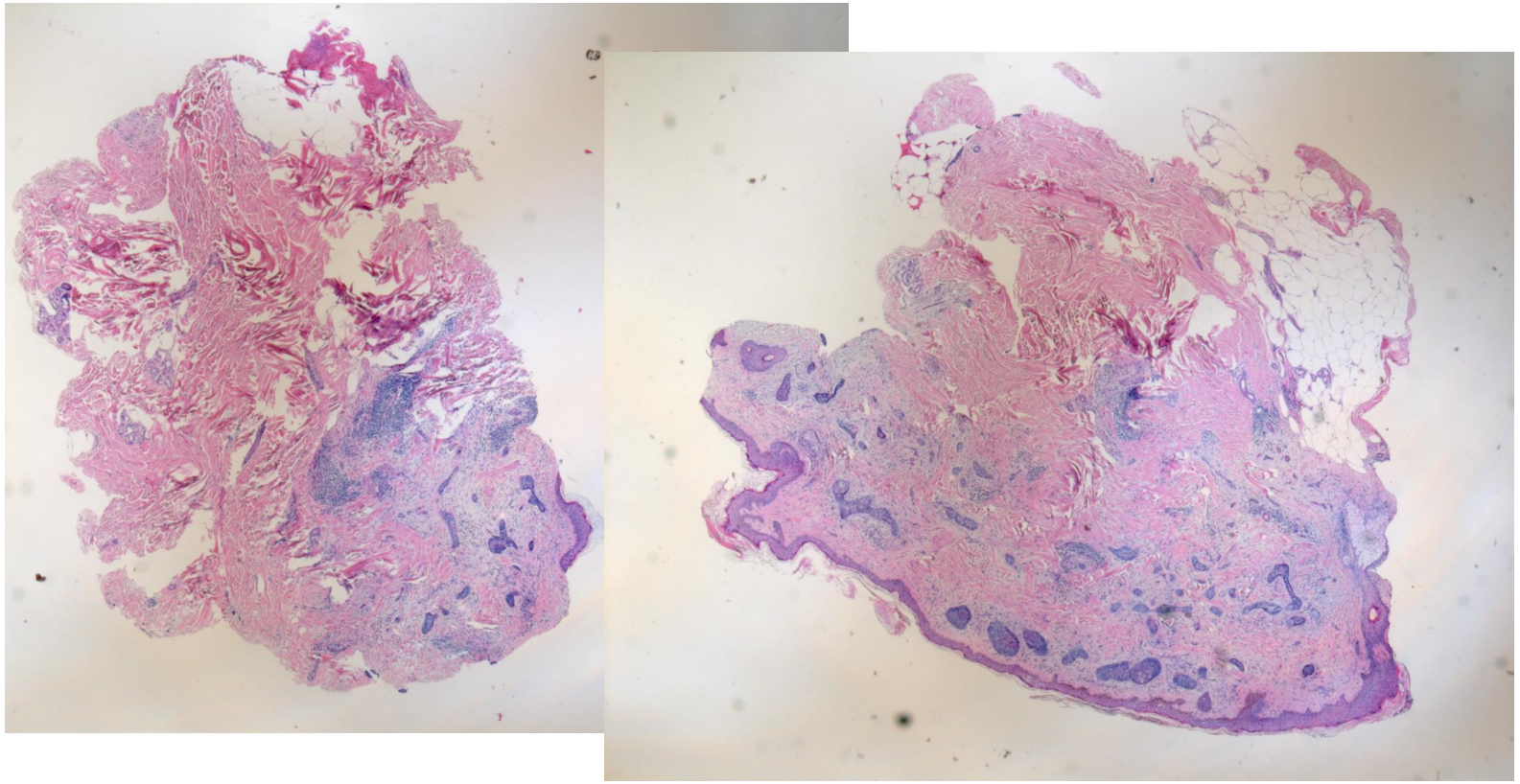

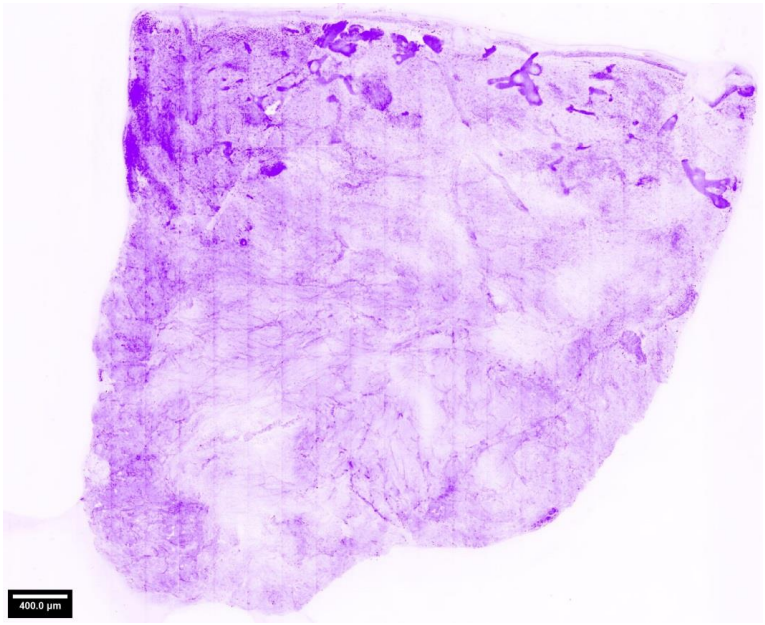
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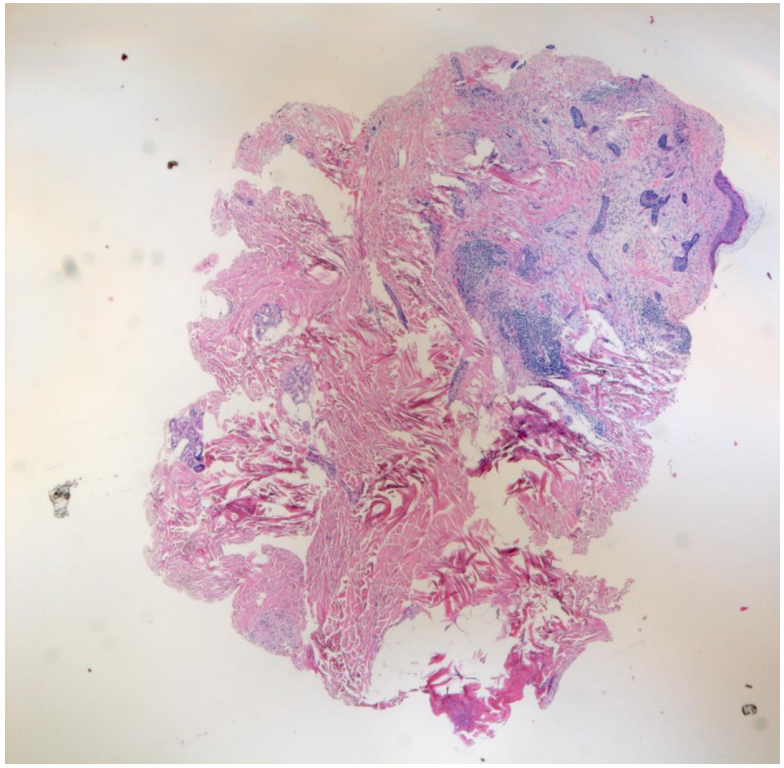

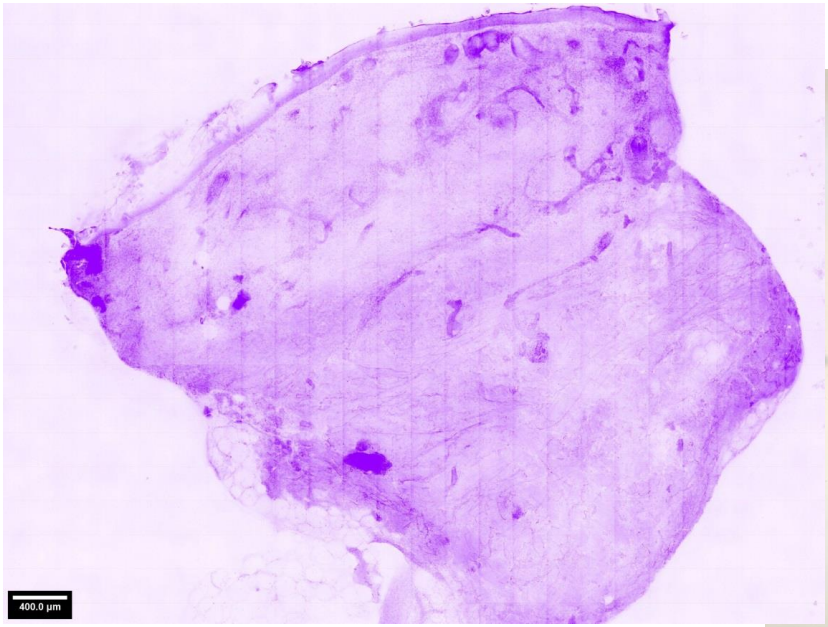
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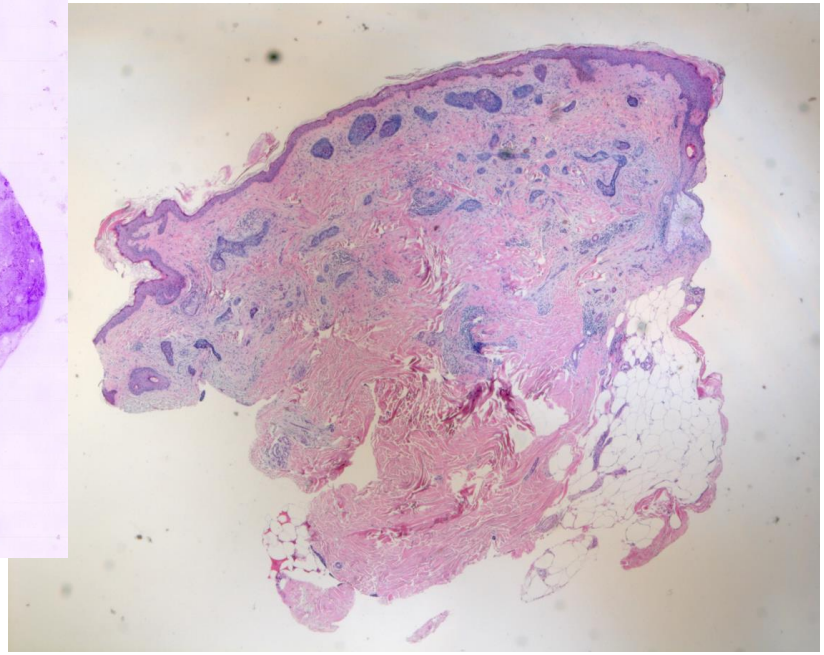

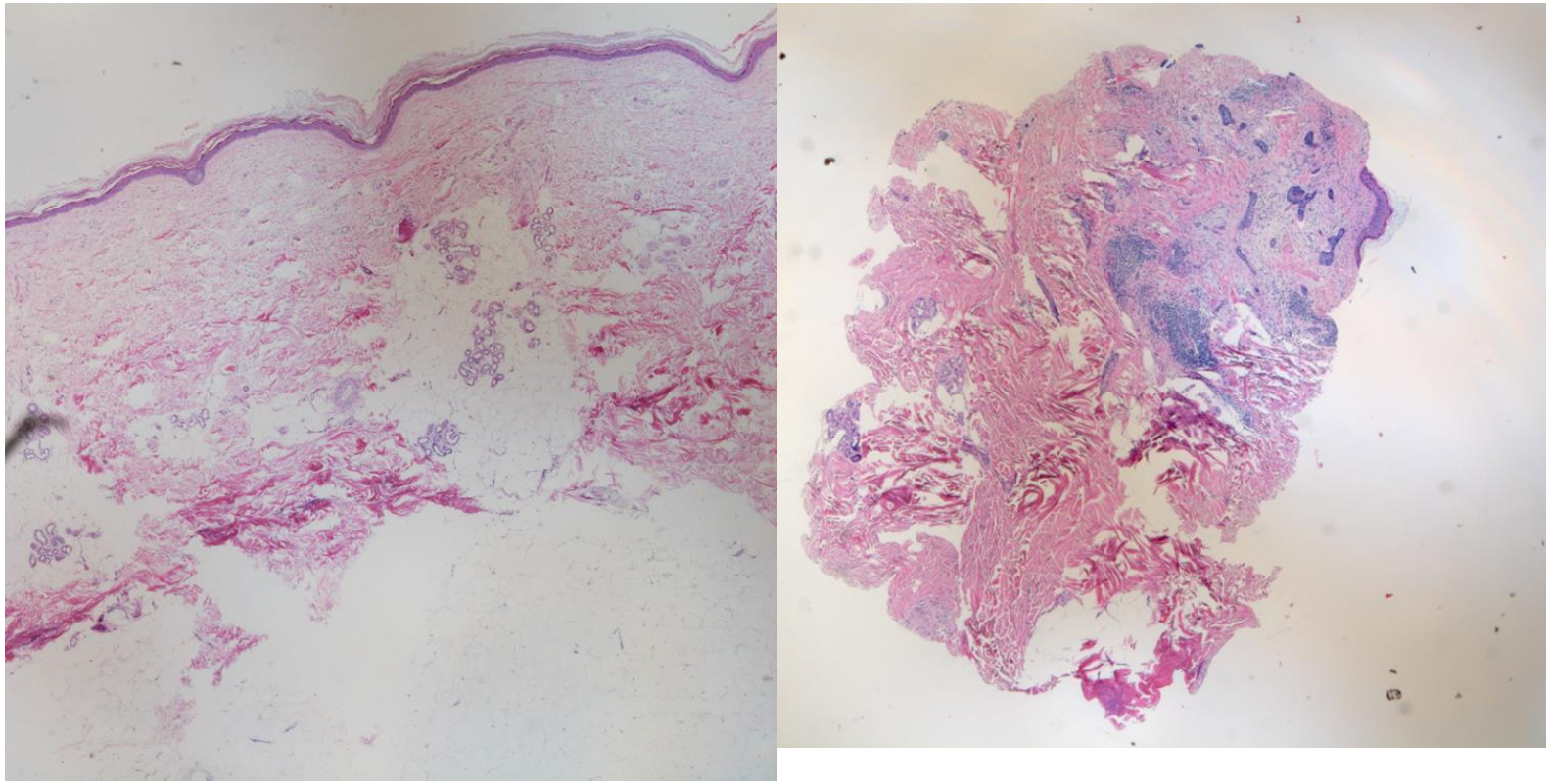

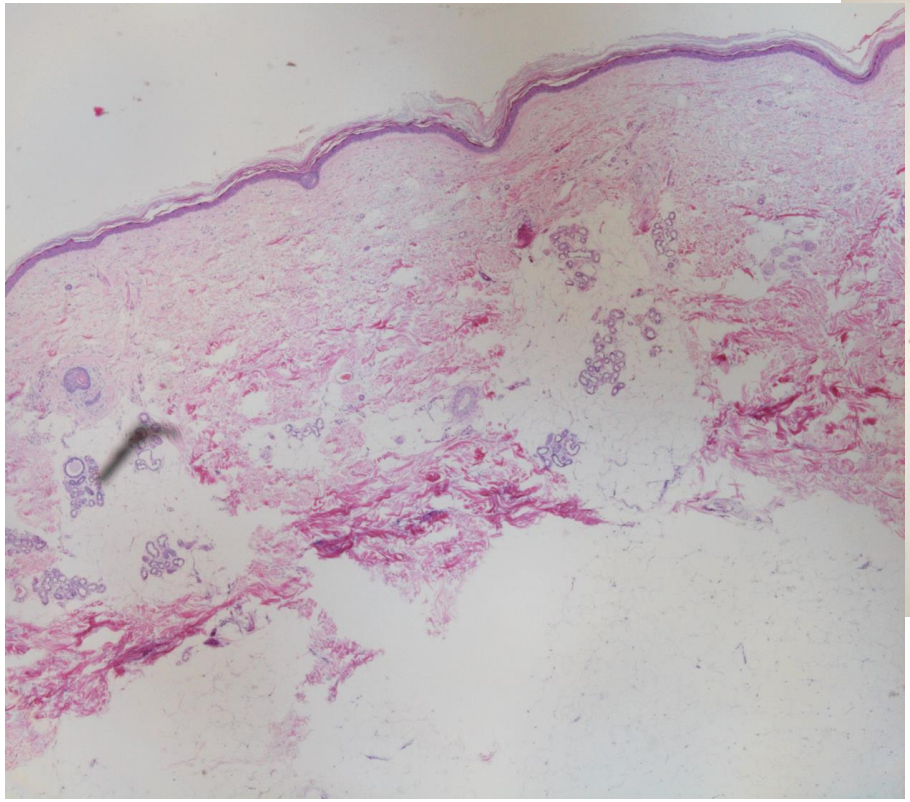

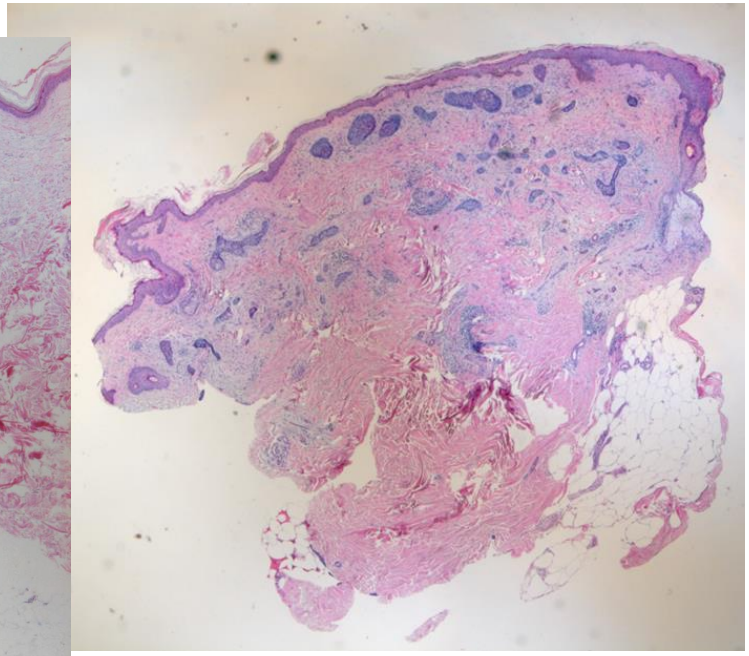

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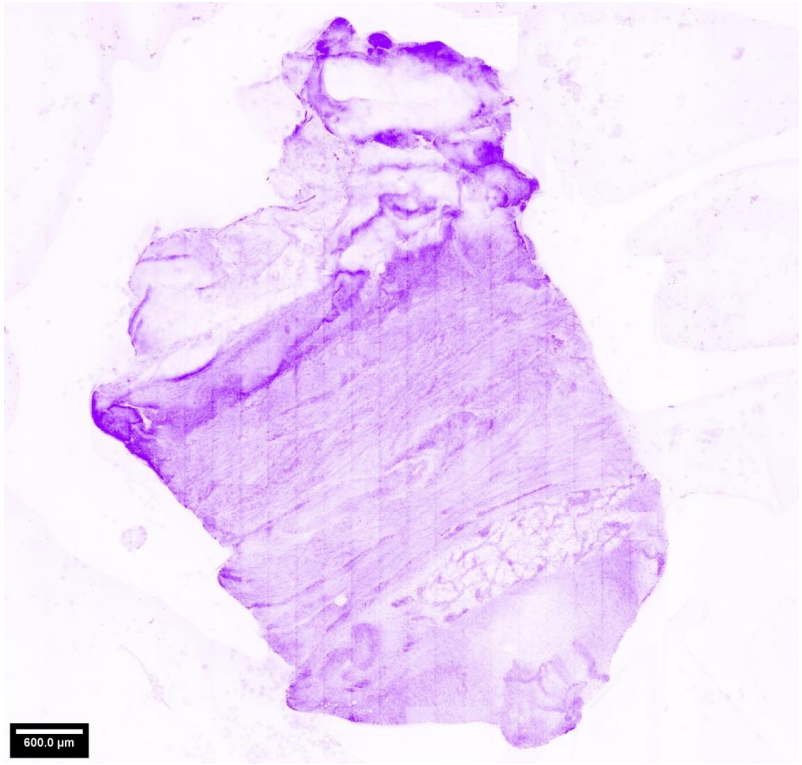

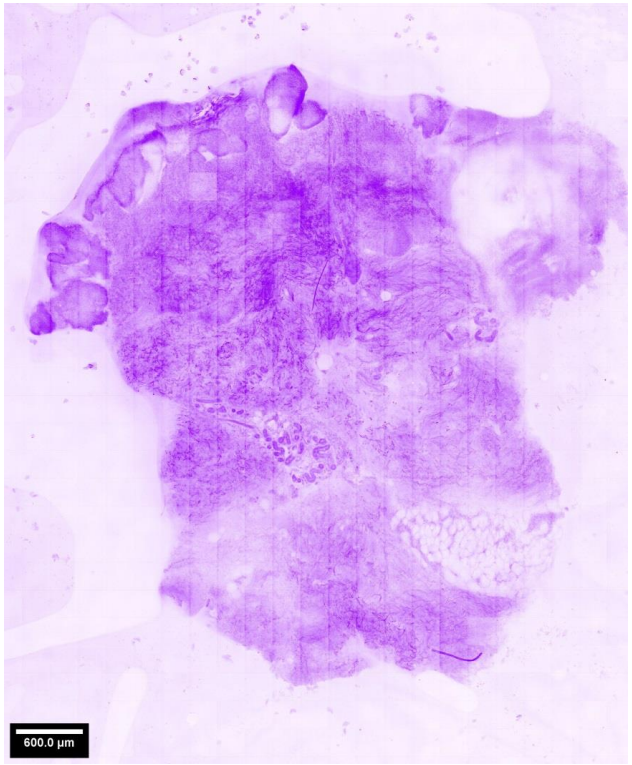

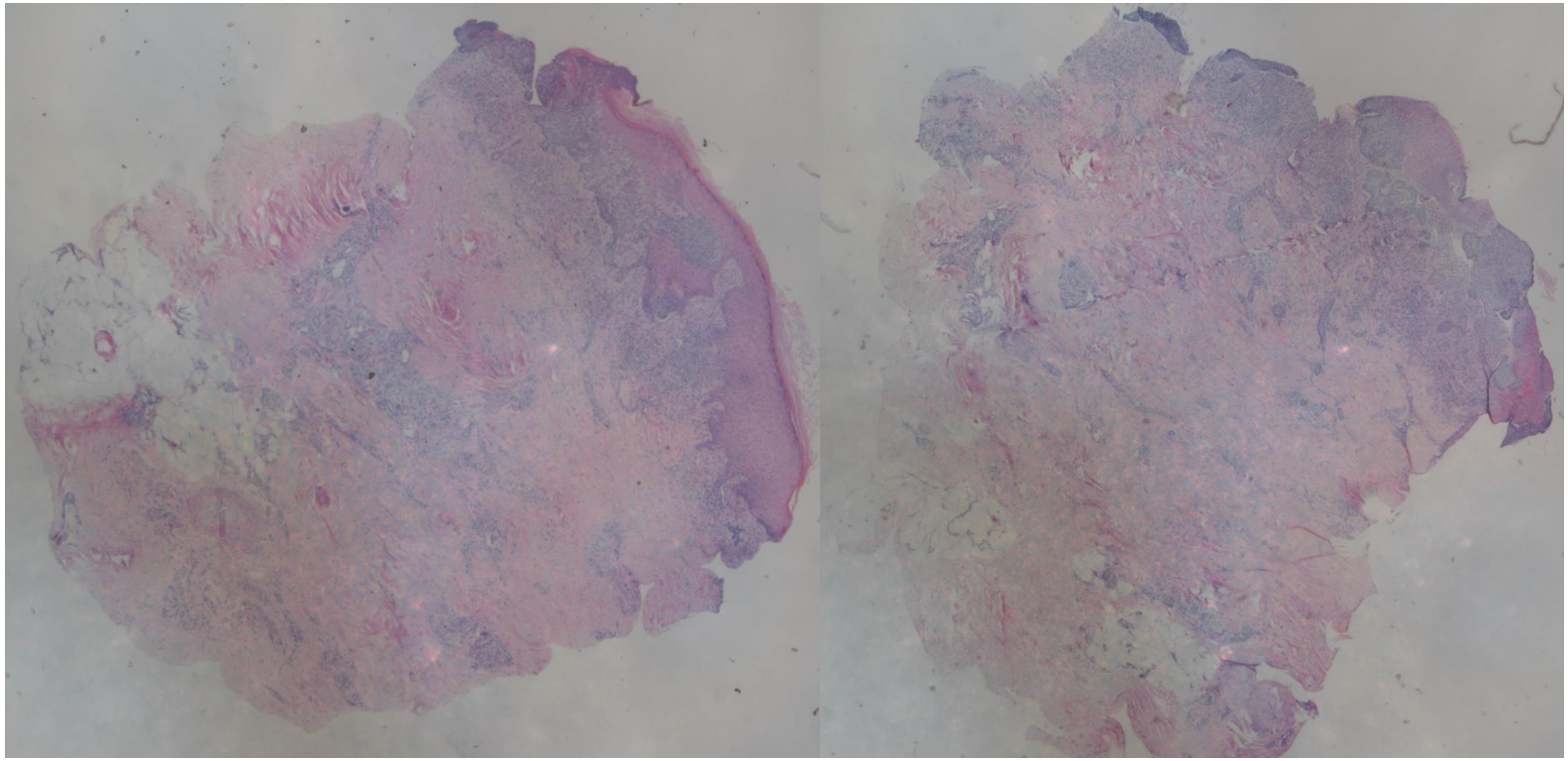

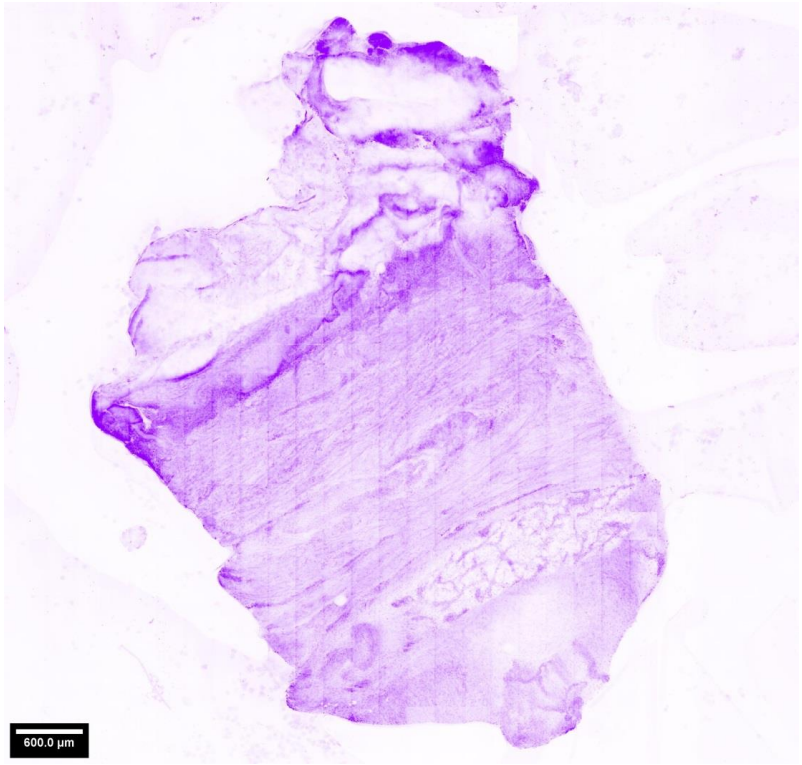
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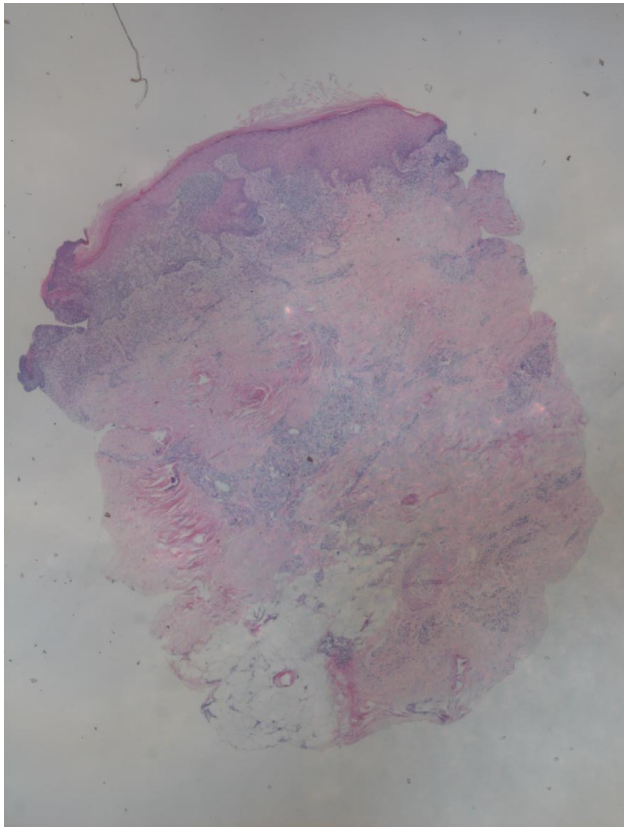

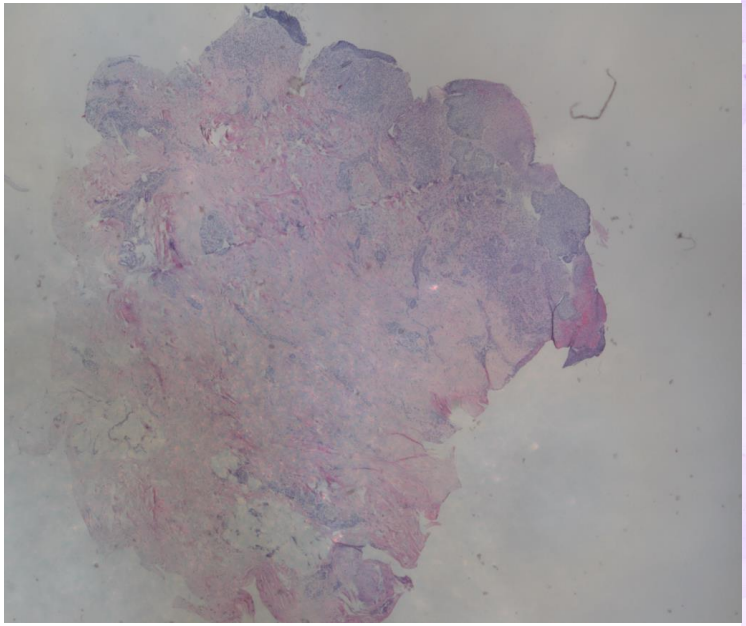

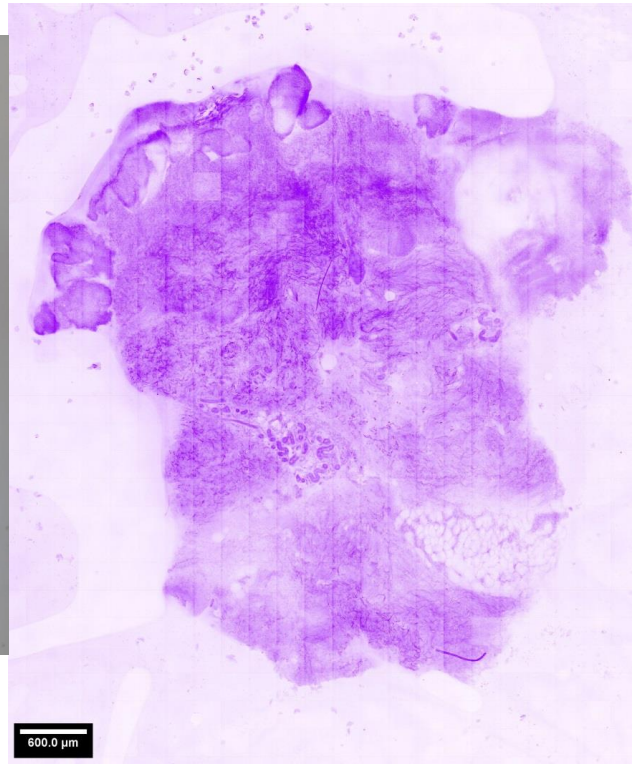
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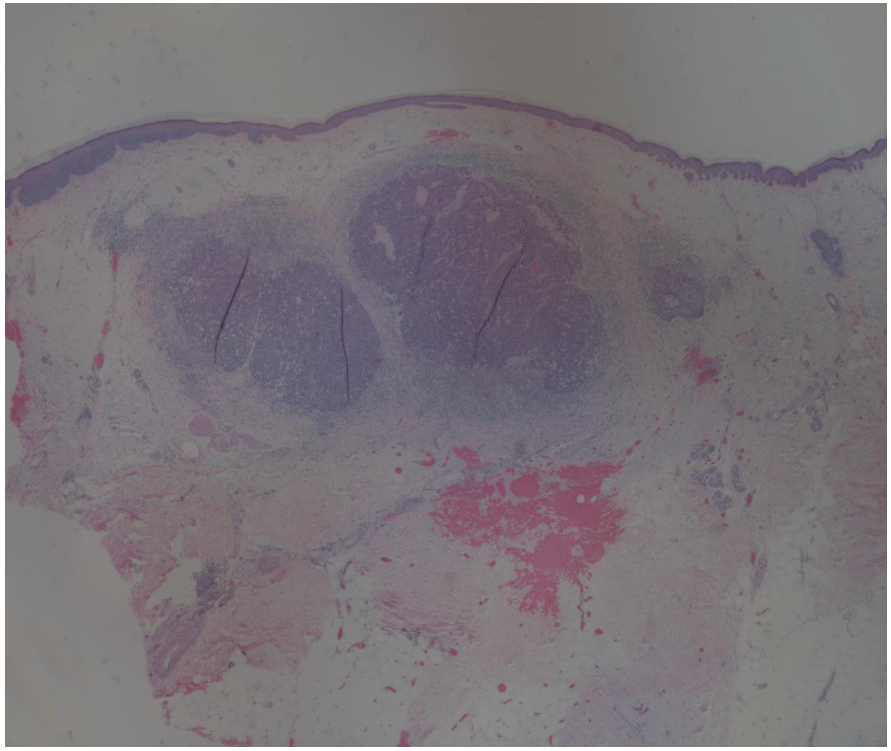

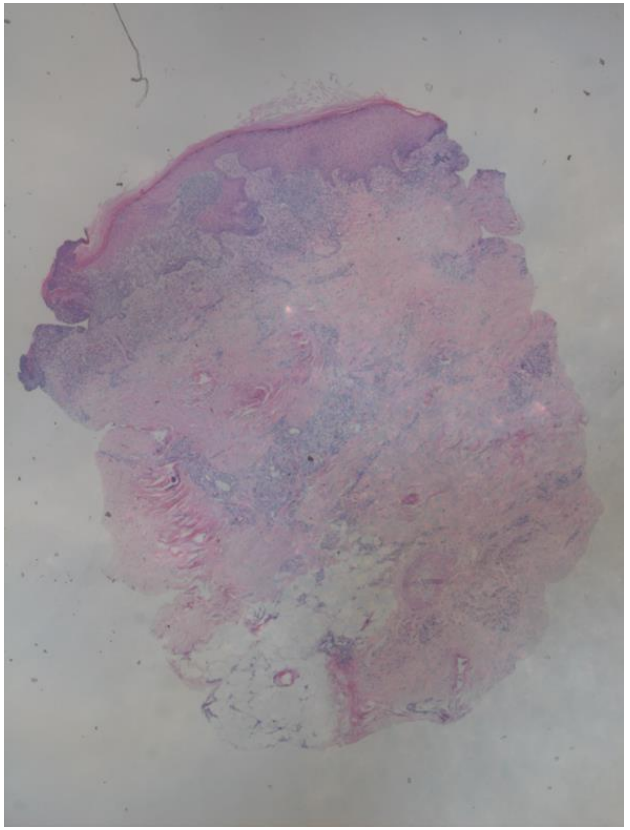

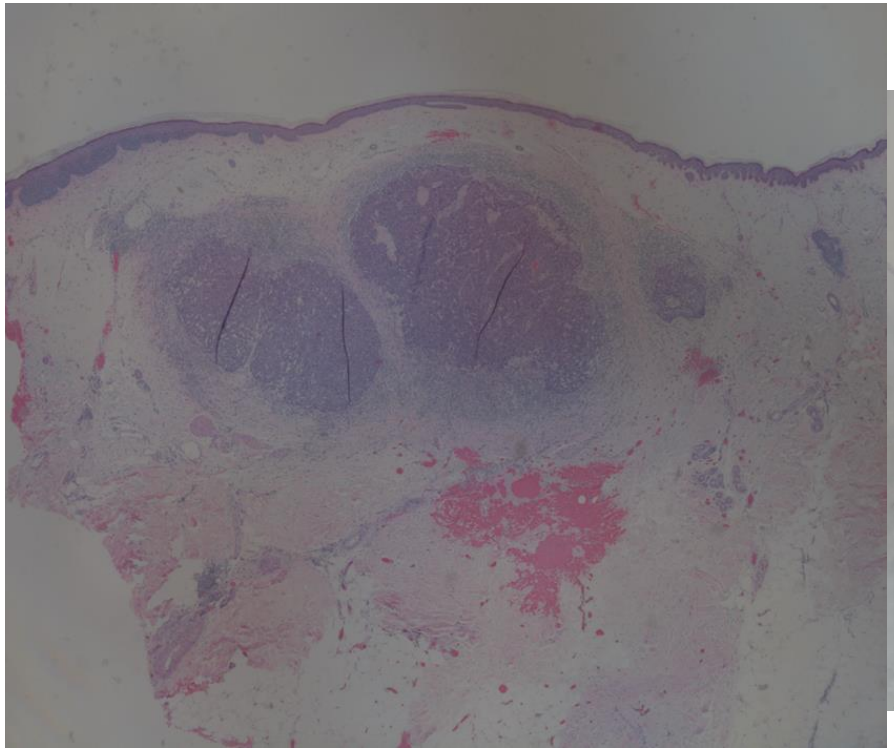

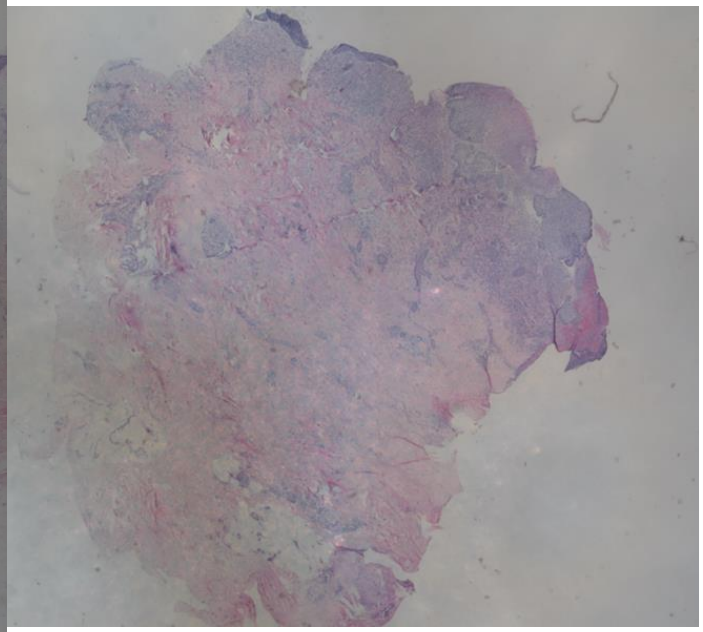

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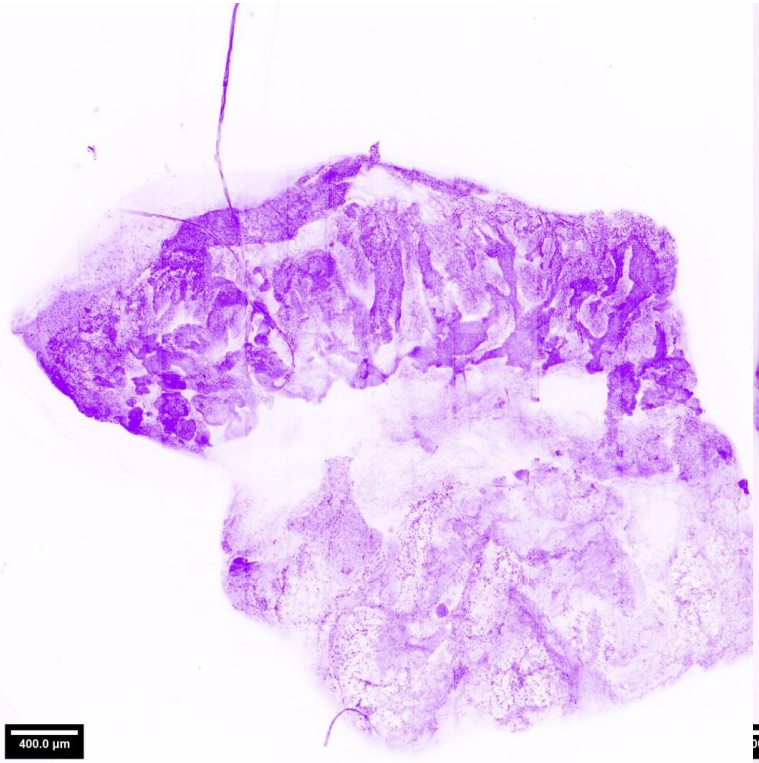

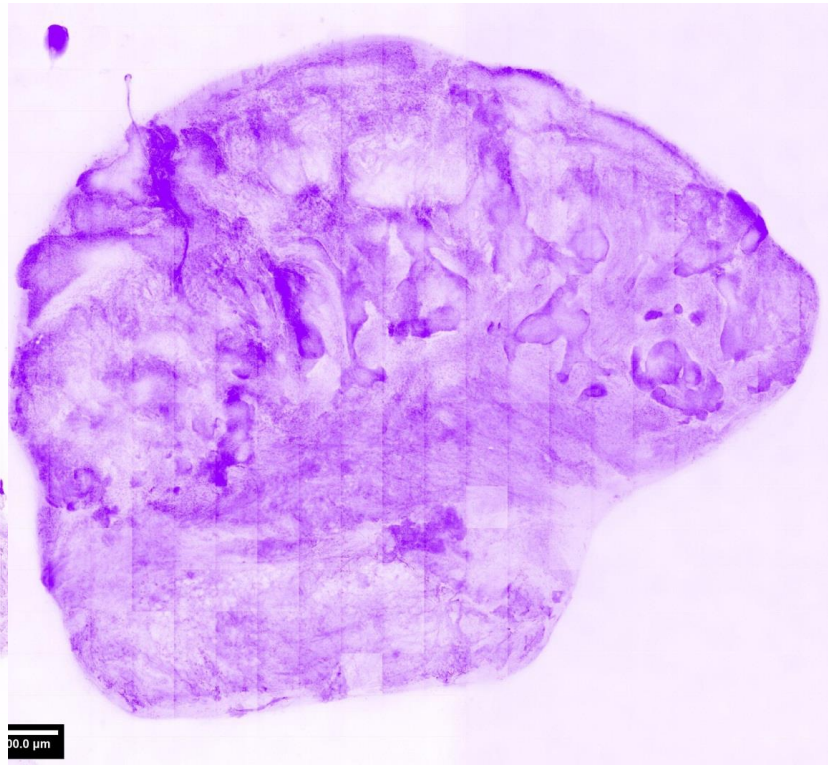

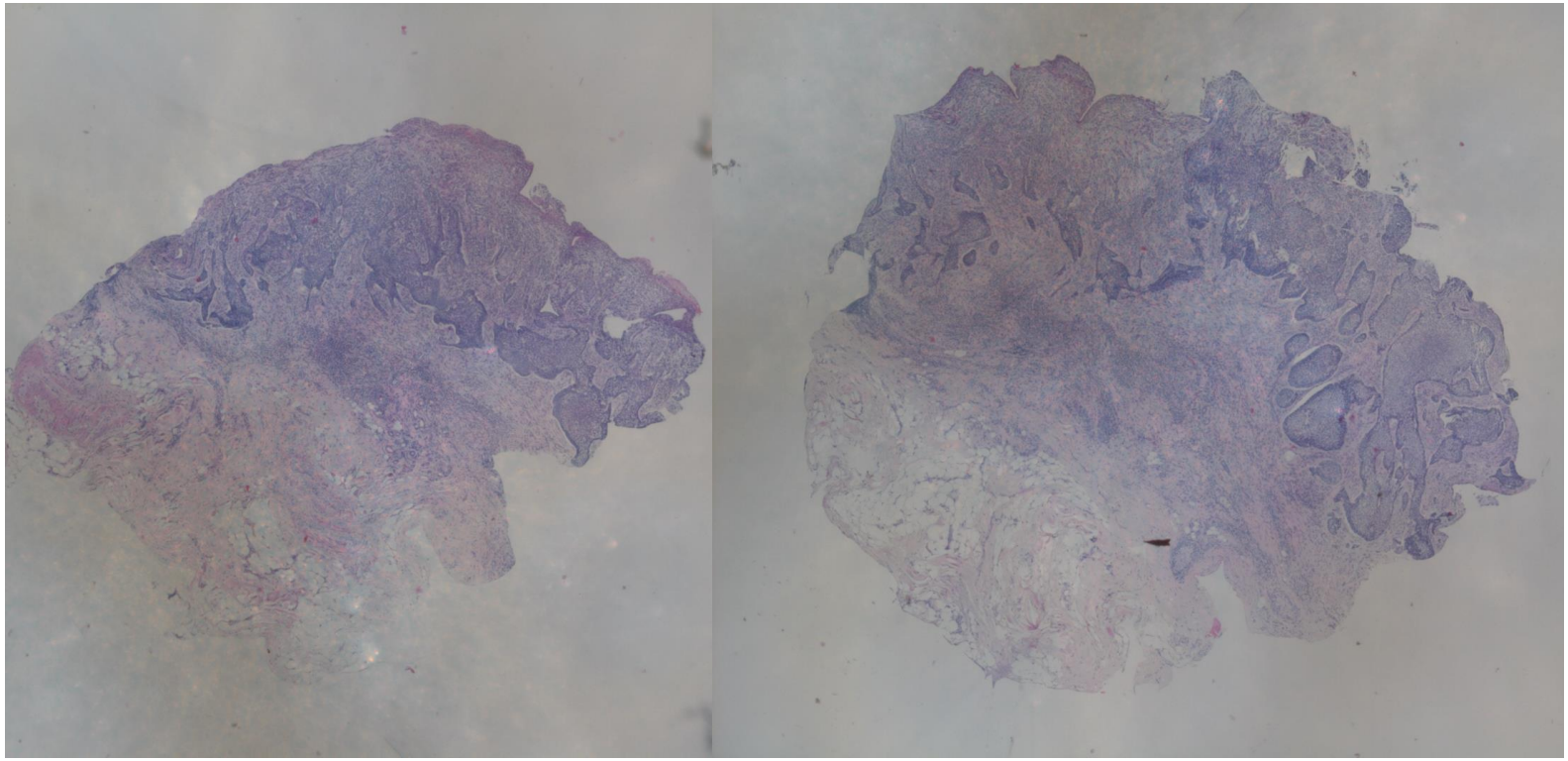

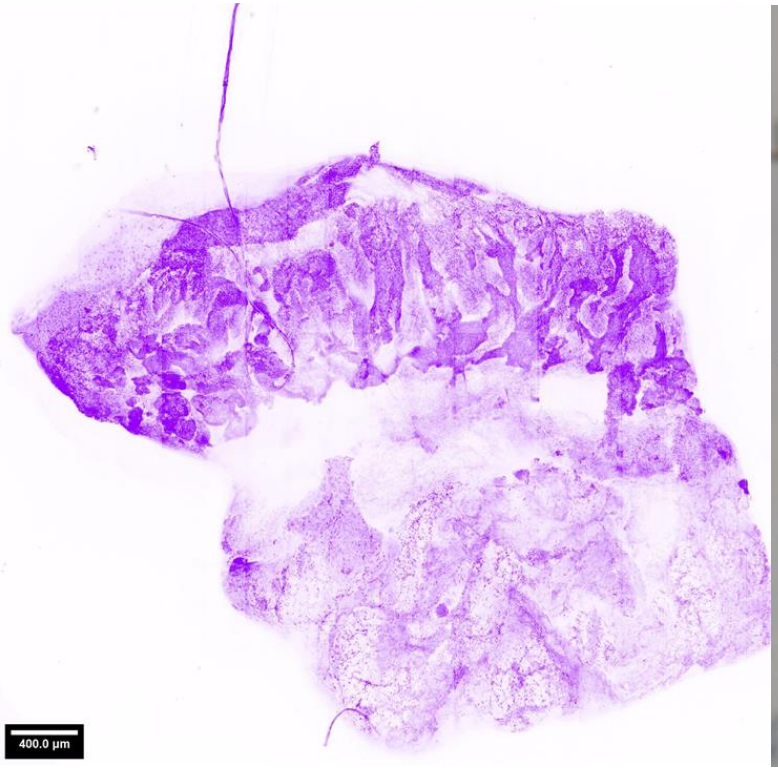
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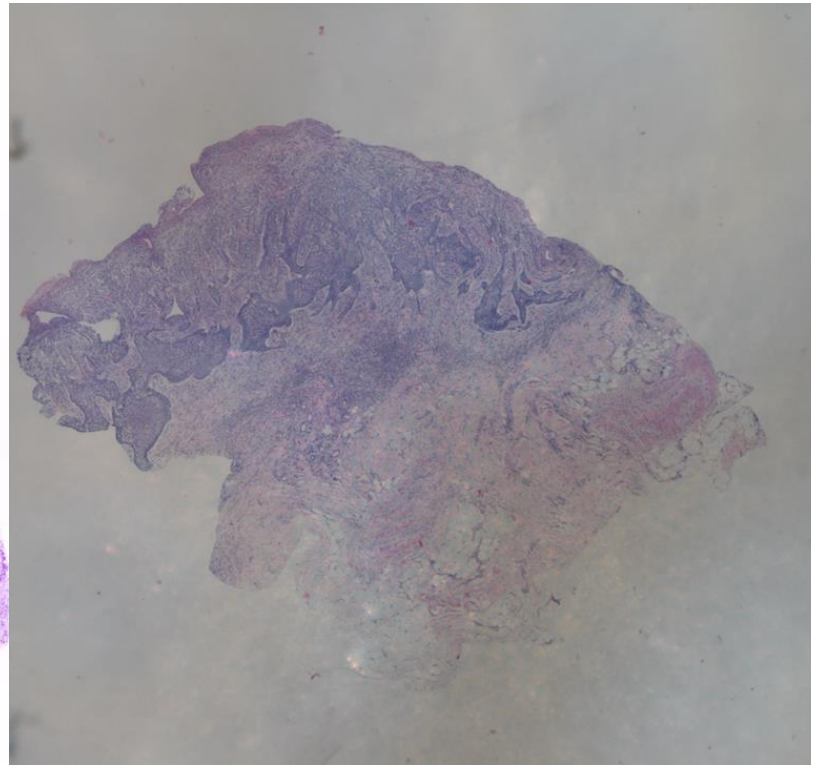

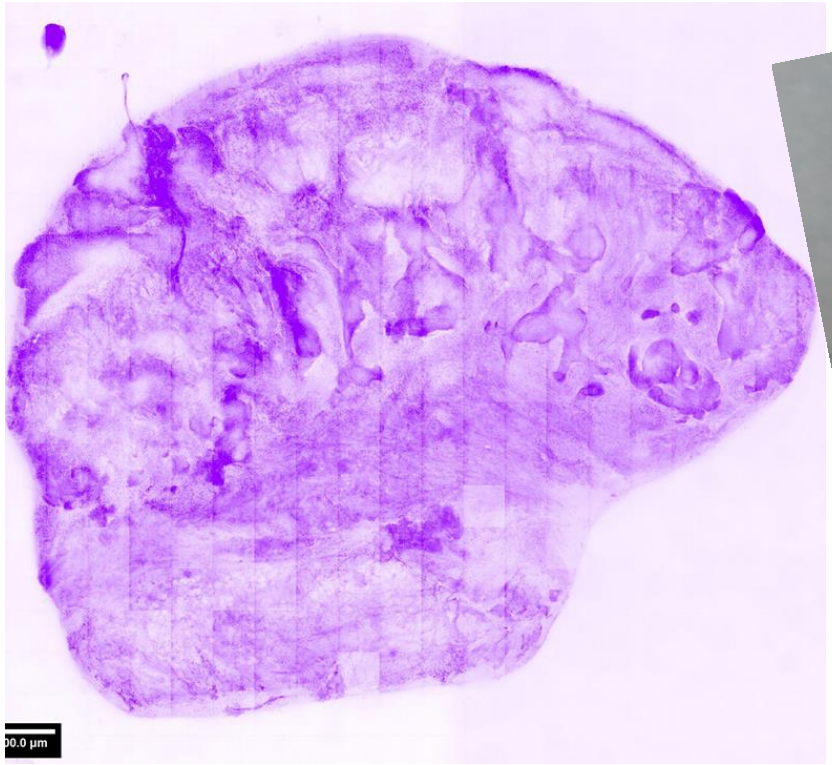
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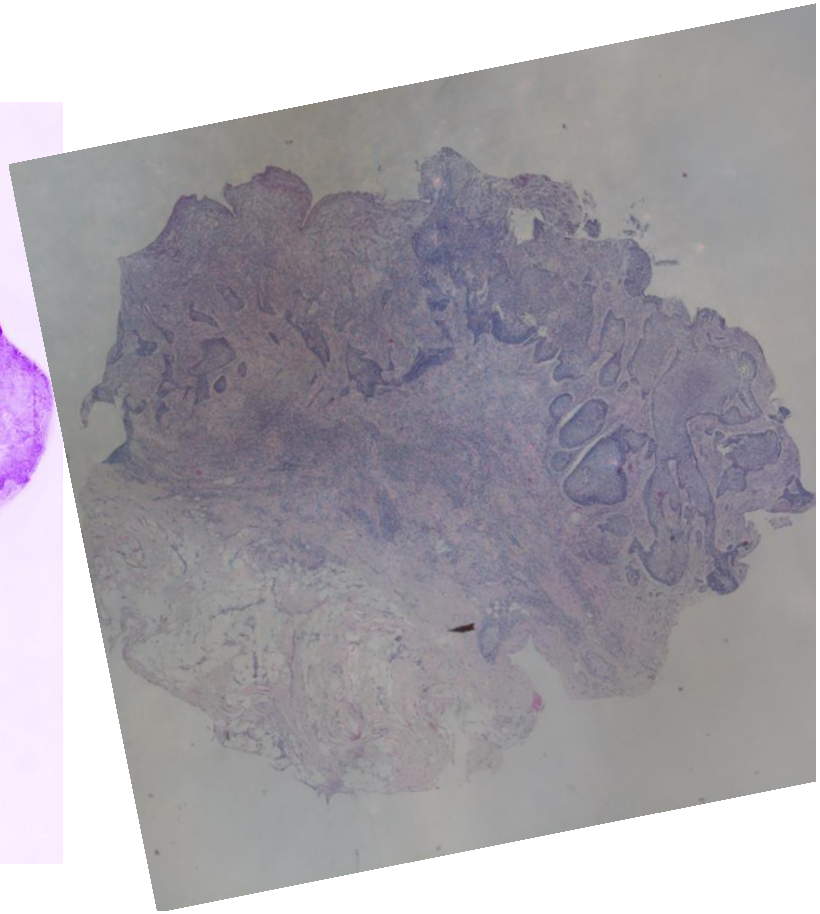

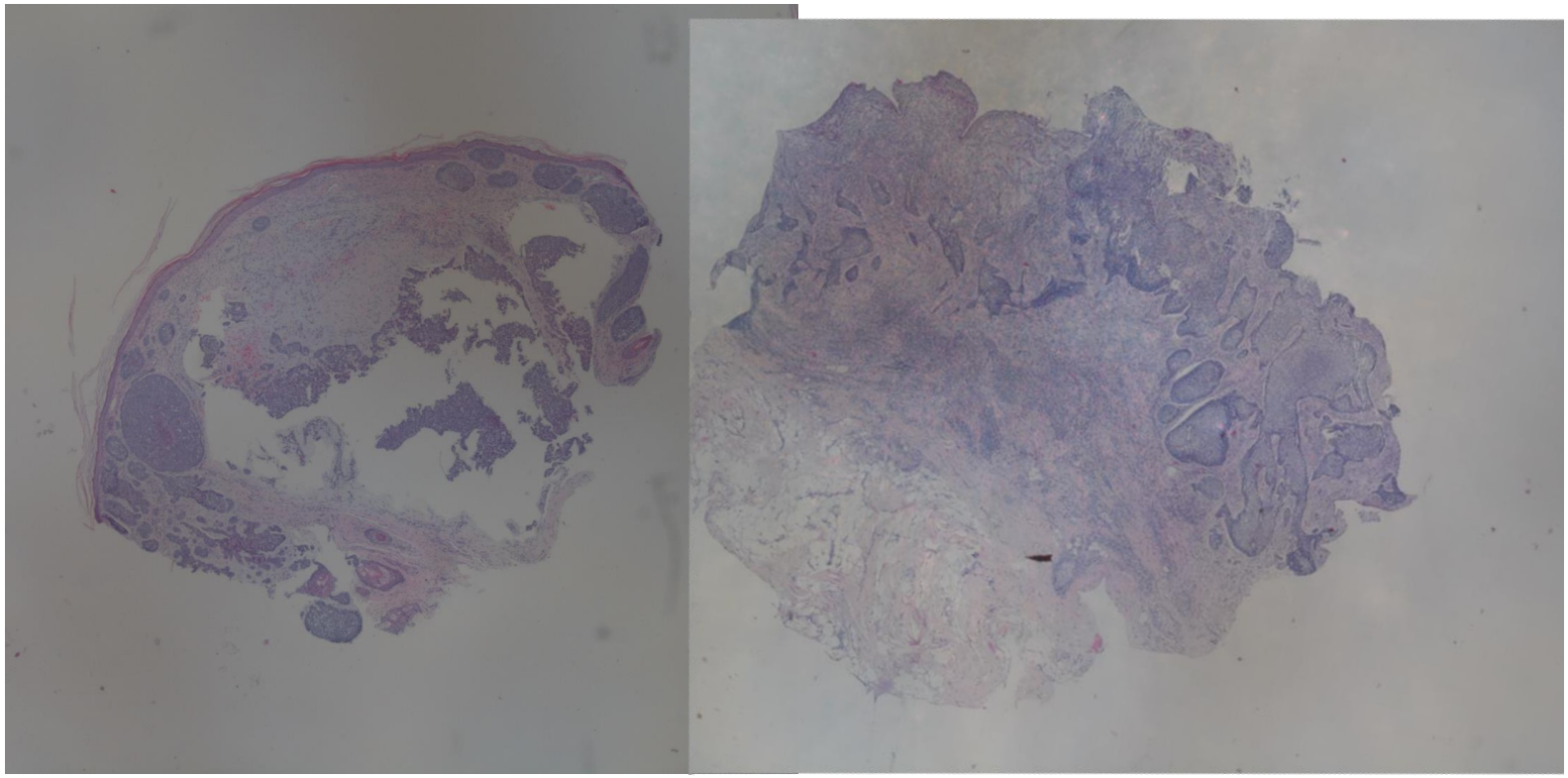

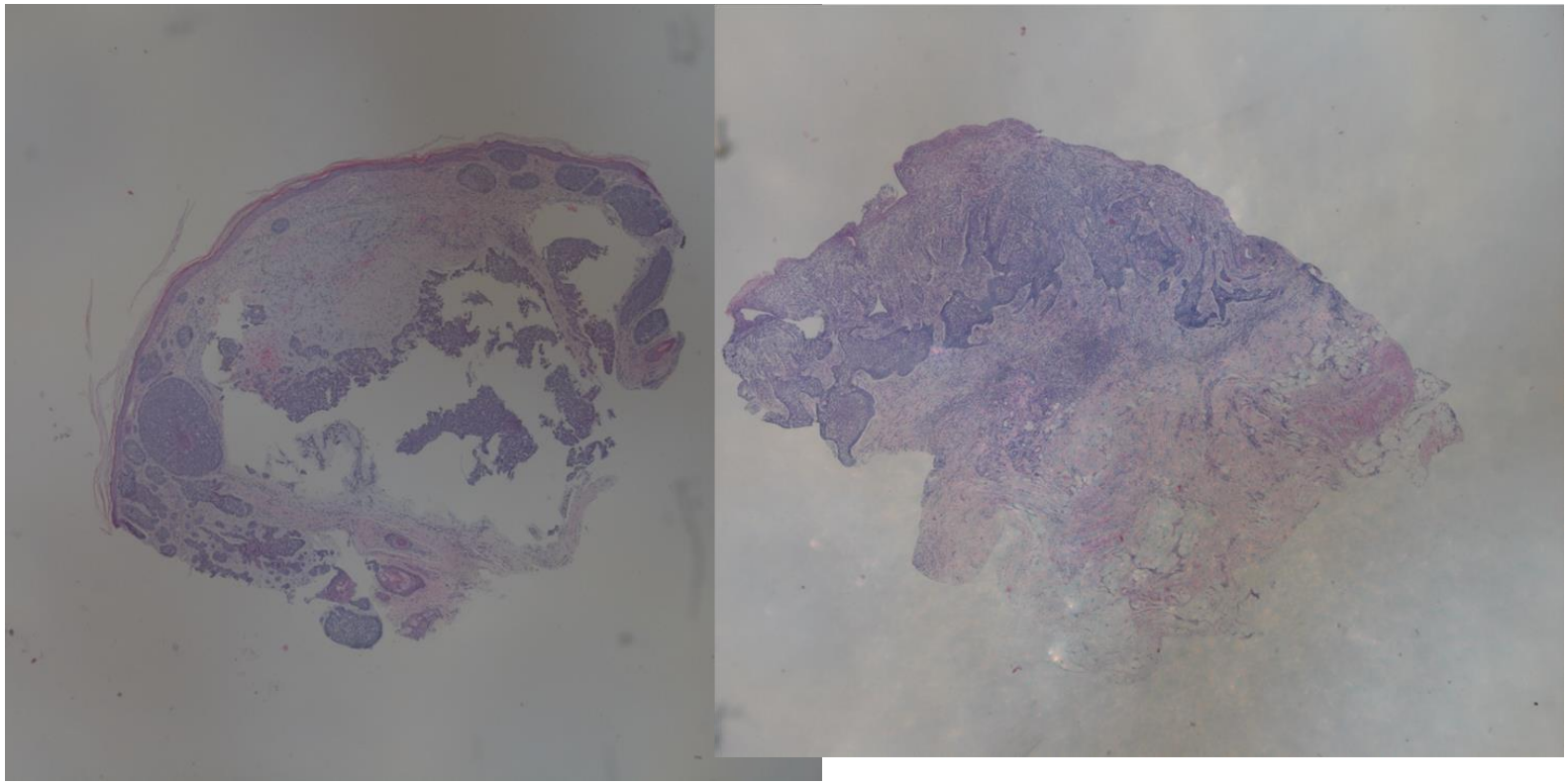

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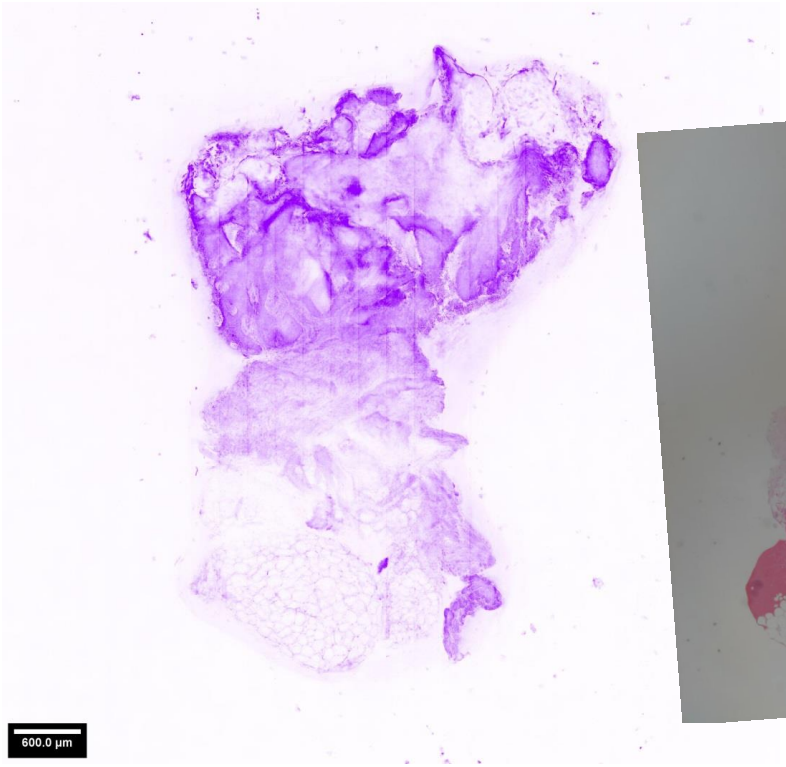

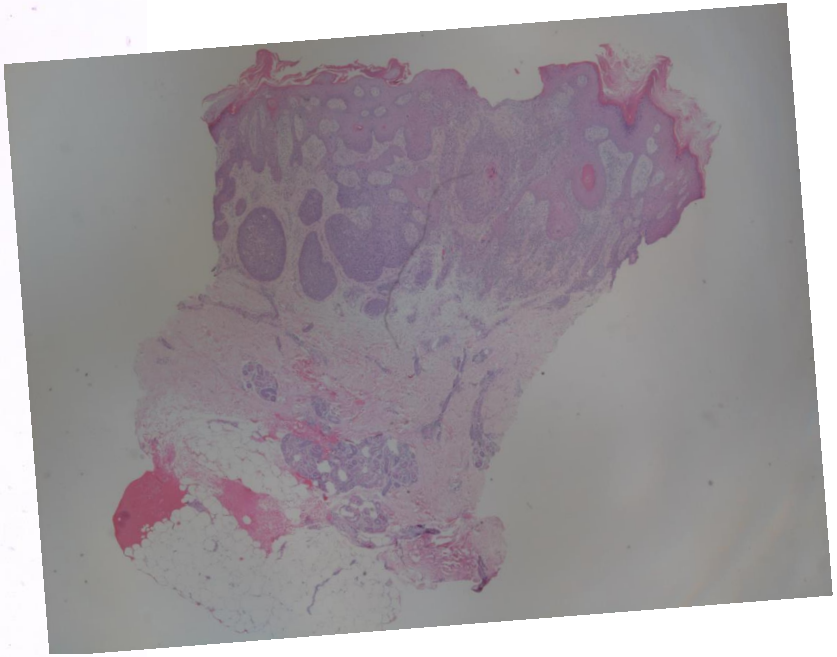

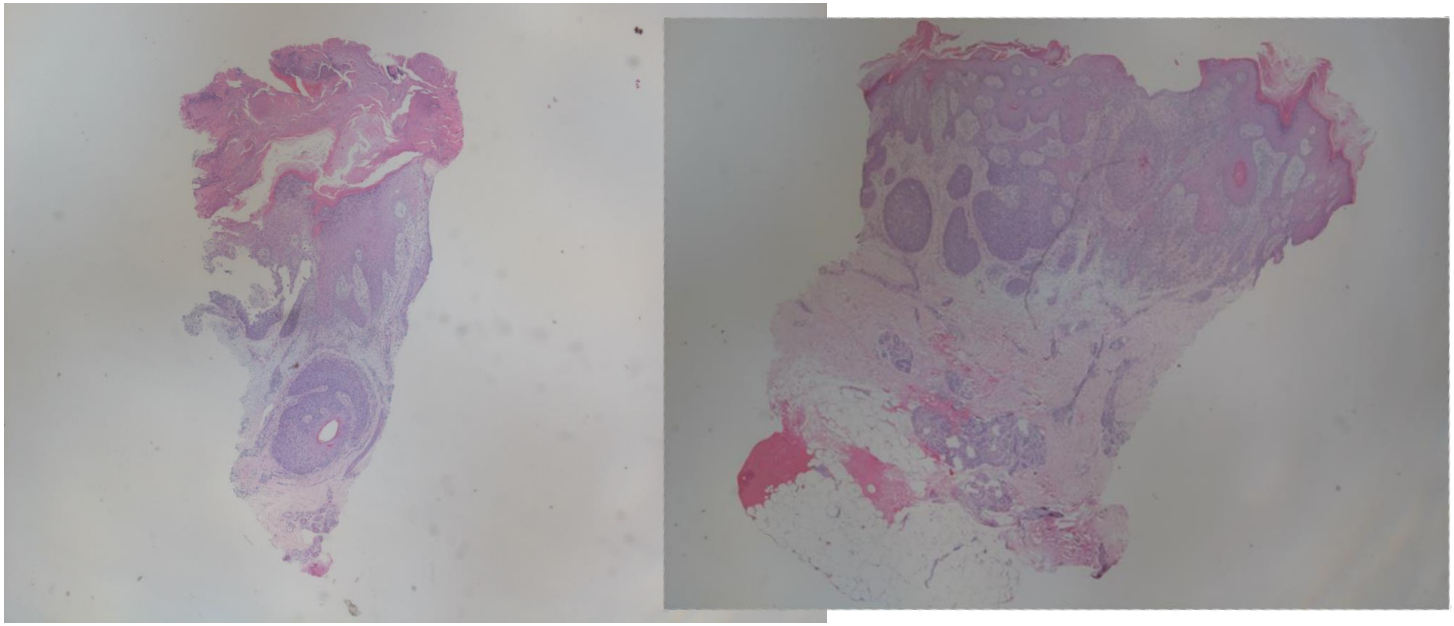

DS