Hematoxylin Validation

Premium Hematoxylin - 7110

Manufactured by

scigen®

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Scigen® Premium Hematoxylin Validation

An essential requirement in the histopathology laboratory is that the hematoxylin stain quality must be consistently repeatable for all batches received from the manufacturer. This stain stability allows the laboratory to add the new batch of hematoxylin stain to their automatic slide stainer with no adjustment in dipping time. Tissue staining should be easy, with the resultant slides held to a high standard, demonstrating unique tissue morphology for pathological diagnostics. This applies to the complete range of specimen types and sizes, ranging from needle biopsies to fragile tissues to significant dense tissue. In busy laboratories, histological techniques are balanced against increasing work demands to reduce turnaround times, process more specimens, and complete more runs in the workday.

Scigen® Premium Hematoxylin Product Characteristics

Scigen® Premium Hematoxylin (7110) is a non-precipitating, progressive, mercury-free stain formulated to exceed the performance of Gills and Harris Hematoxylins. It is an excellent nuclear stain for routine hematoxylin and eosin, frozen section, and IHC background staining. Our Hematoxylin produces incredible nuclear detail, with nuclear chromatin staining a crisp blue-purple with exceptional characteristics and provides the flexibility of Harris and Gills stains without staining acid mucopolysaccharides (mucin).

Epredia (Richard-Allen Scientific) Hematoxylin (7211) is a rapid, progressive hematoxylin that has gained a vast market share and notoriety in the Histology and Cytology fields. The product is a hybrid between classical Harris and Gill formulations: it provides the classic intensity and hues of a Harris Hematoxylin formulation and the rapid and progressive qualities of a Gill Hematoxylin formulation. It will also provide a consistent, well-delineated nuclear stain and not require daily filtering.

Validation Method

Staff developed standard operating procedures and evaluating tools to address the selected criteria thoroughly. This involved pathologists and histo-technologists from several external laboratories and in-house scientists to assess processed blocks and stained sections from all processing runs. The evaluation involved duplicate sets of matched specimens of various dimensions and tissue types; multiple processing runs were conducted. **Scigen®** Premium Hematoxylin (7110) has been evaluated over a 3-year interval for evidence of adequate hematoxylin stain stability.

Staff evaluated over 1,100 specimen blocks with different processing reagents and their impact on hematoxylin performance when comparing **Scigen®** 7110 to RAS 7211. All reagents were manufactured using the ISO 13485 standard. In addition, slides from many processing runs on different processors were presented to several pathologists for a blind assessment of Hematoxylin stain quality. Furthermore, optical stain density studies were conducted to establish the repeatability and reproducibility precision intervals.

Precision

Repeatability: The difference between successive results, obtained by the same technician with the same apparatus under constant operating conditions on identical tissue, would, in the long run, in the normal and correct operation of the test method, exceed the following value only in one case in twenty: 0.5% optical variation in transmission.

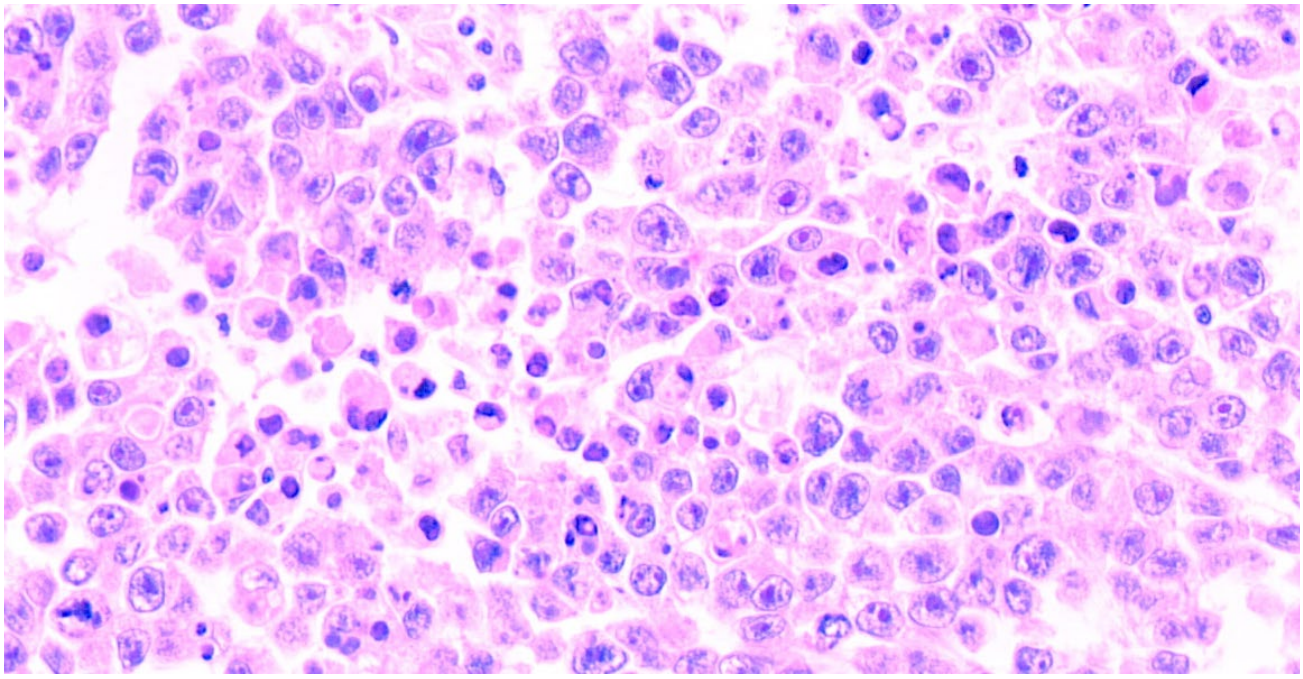
Reproducibility: the difference between two, single and independent results obtained by different operators working in different laboratories on identical tissue, would, in the long run, in the normal and correct operation of the test method, exceed the following value only one in twenty: 2.7% optical variation in transmission.

Conclusion

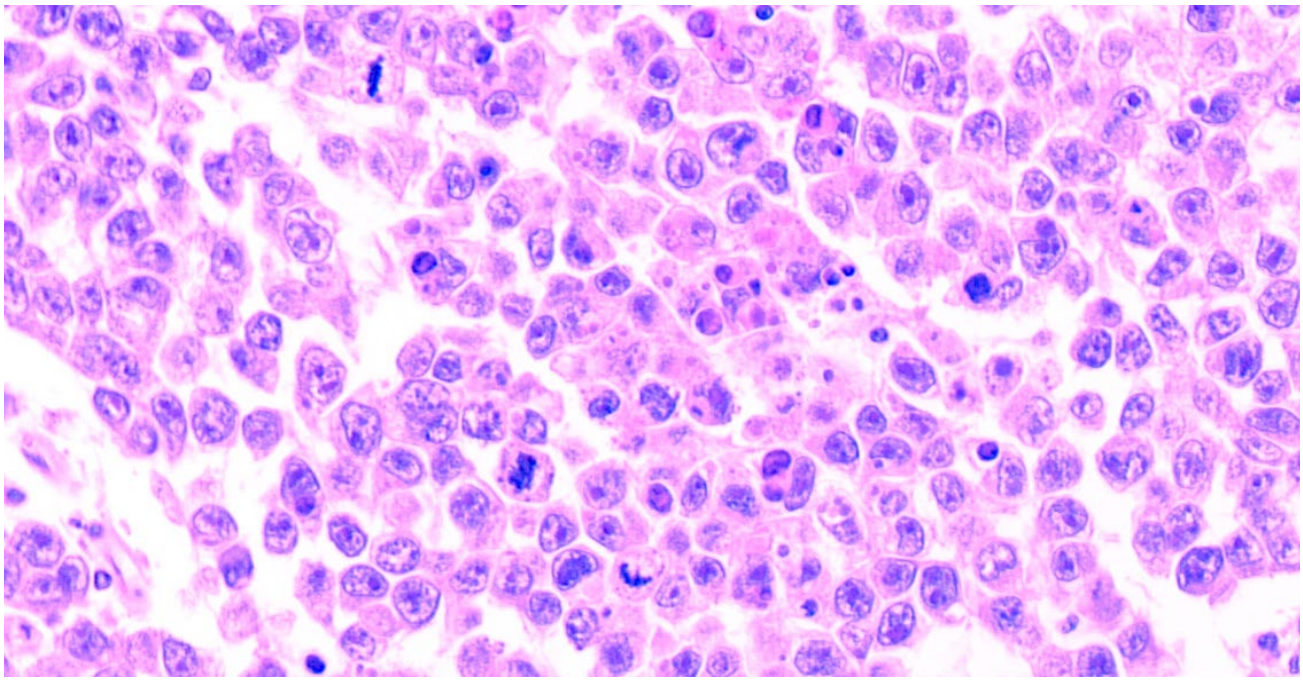
Pathological examination coupled with spectroscopic analysis demonstrated that **Scigen® Premium Hematoxylin (7110)** is equivalent to Epredia (Richard-Allen Scientific) Hematoxylin (7211). Our evaluation involved nineteen (19) production batches over three years. Studies showed that the two products produced matching results. The analysis was two-fold. First, we evaluated the 7110 and 7211 performances in a Reproducibility study between different laboratories. Reproducibility studies are more complex analyses because they involve different equipment and operators. Secondly, spectroscopic analysis was conducted on the tissue specimens, and the slide study established a transmission interval of less than 2.7% optical variation between hematoxylin transmission. Blind Pathological examination also validated 7110 performances. Below are a few slide comparisons used in the reproducibility study.

After establishing our 95% confidence interval for the reproducibility study, our validation studies focused on performance within each laboratory using **Scigen® Premium Hematoxylin (7110)** stain. Again, a repeatability confidence interval was established of less than 0.5% optical transmission between different measurements. The final H&E slide set in our study appears next.

Reproducibility Slide Study

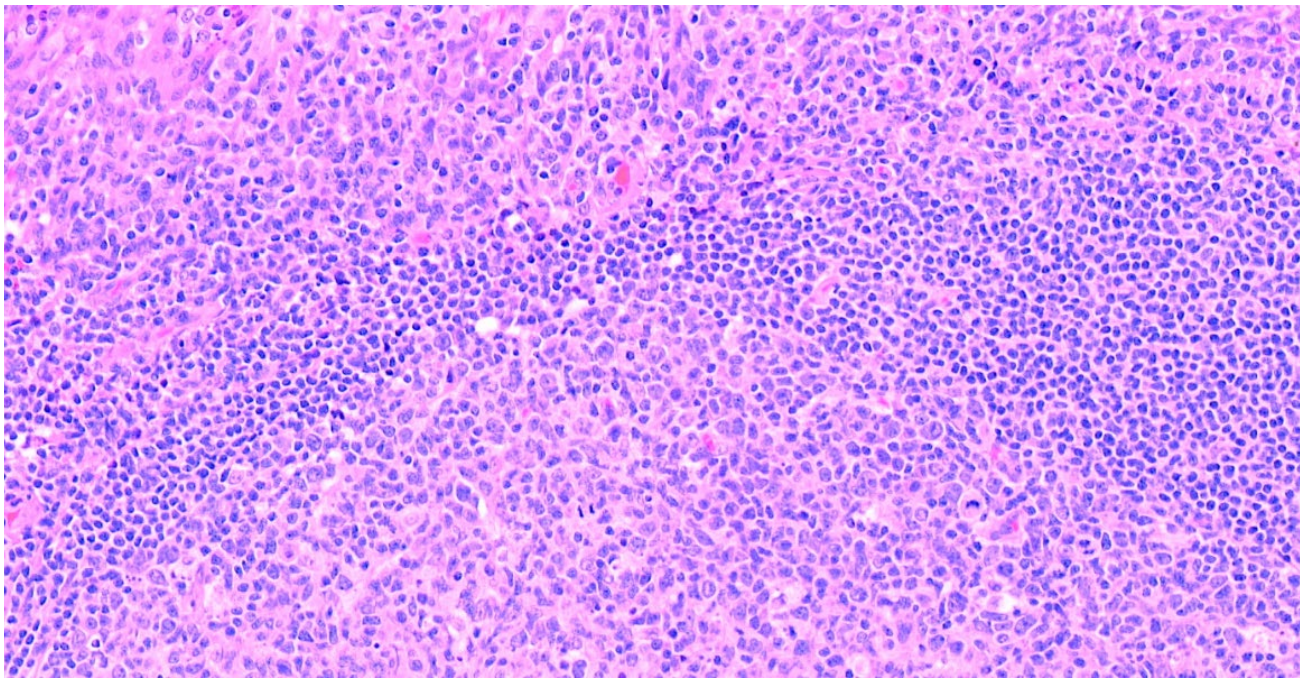


01a. Scigen 7110 at 40x

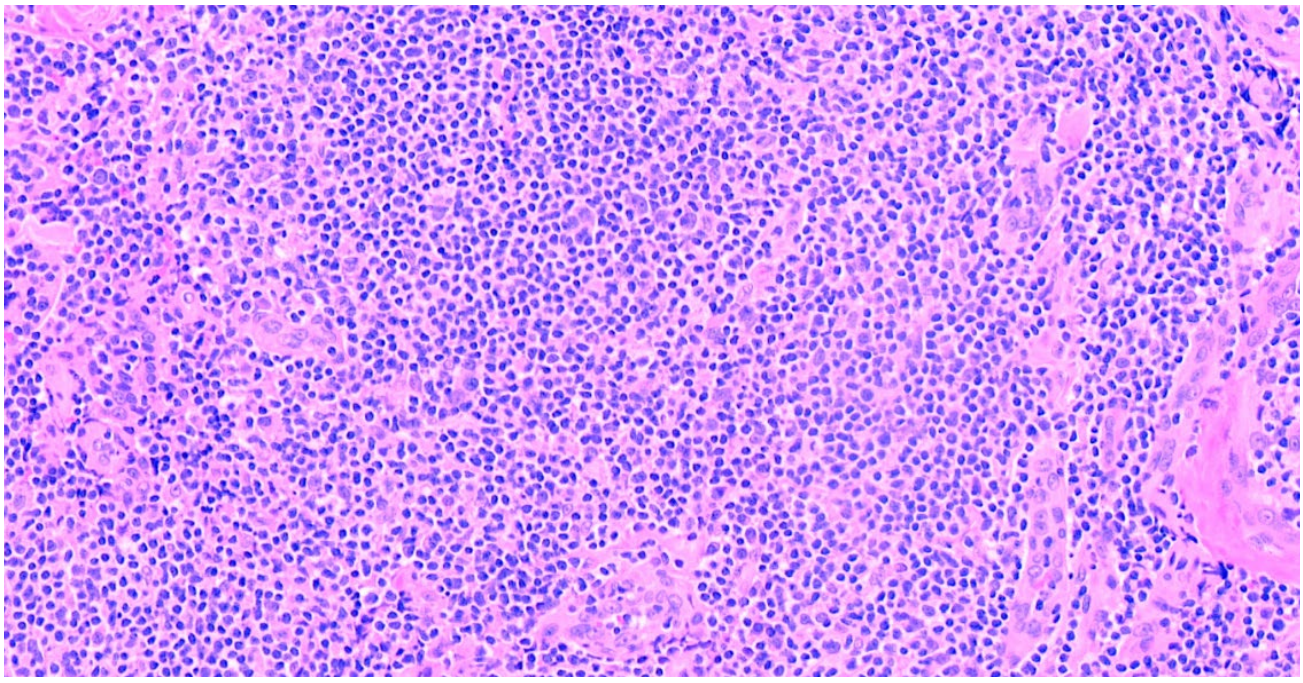


01b. Competitor (RAS 7211) at 40x

Reproducibility Slide Study

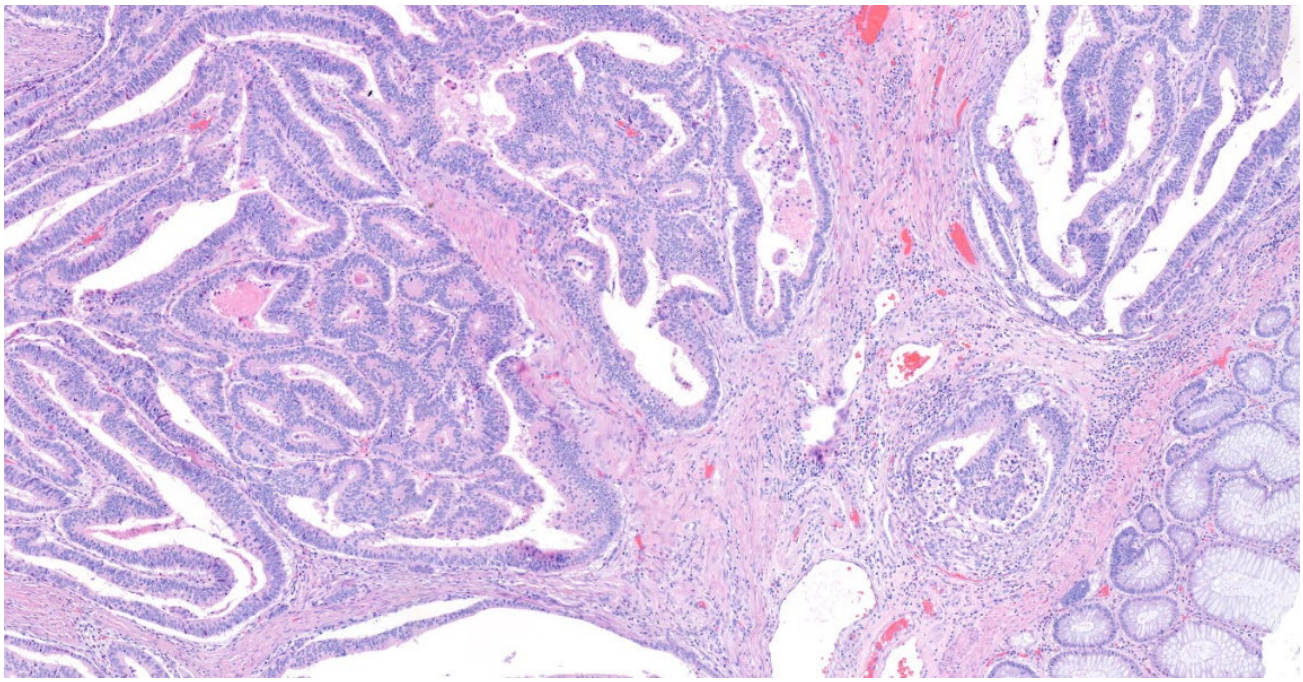


02a. Scigen 7110 at 20x

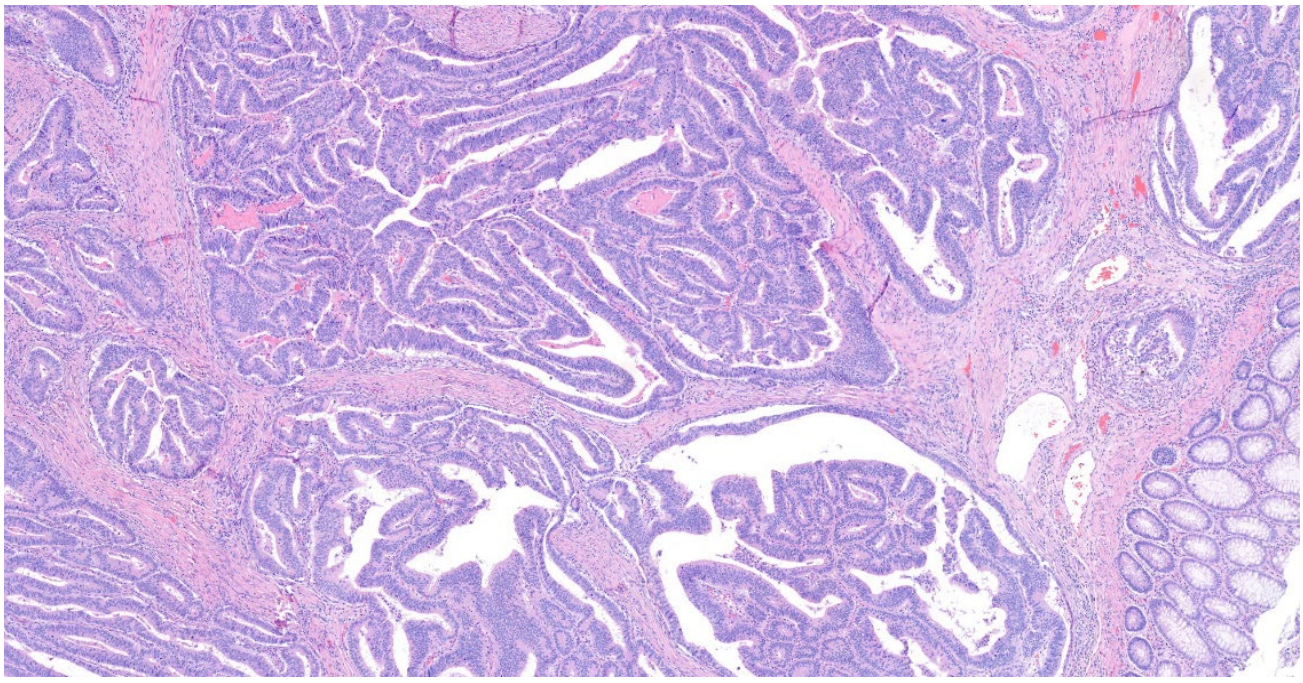


02b. Competitor (RAS 7211) at 20x

Reproducibility Slide Study

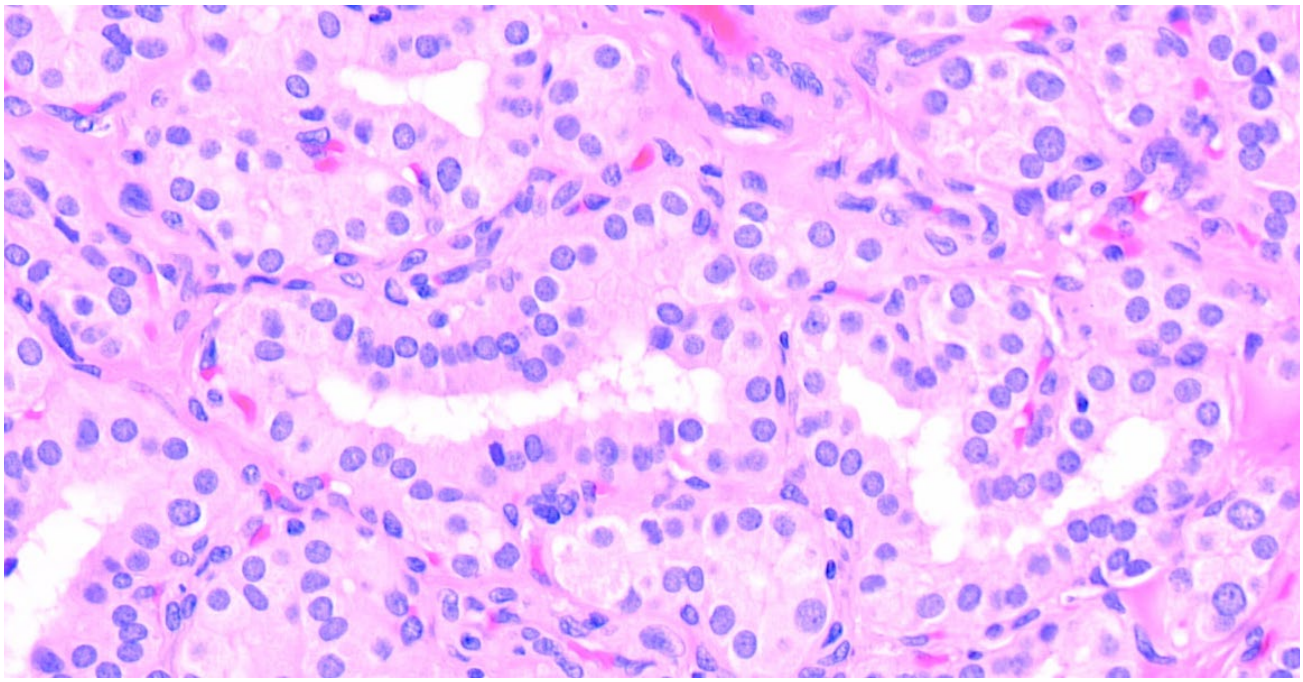


03a. Scigen 7110 at 5x

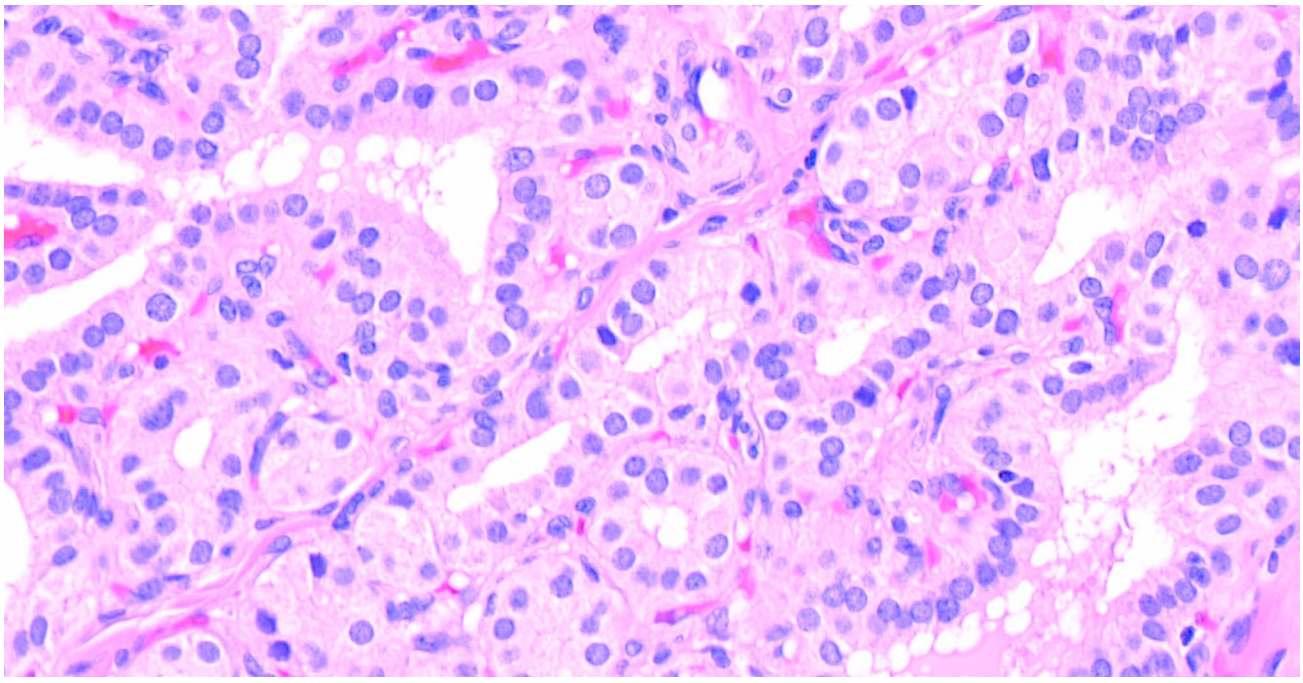


03b. Competitor (RAS 7211) at 5x

Repeatability Slide Study

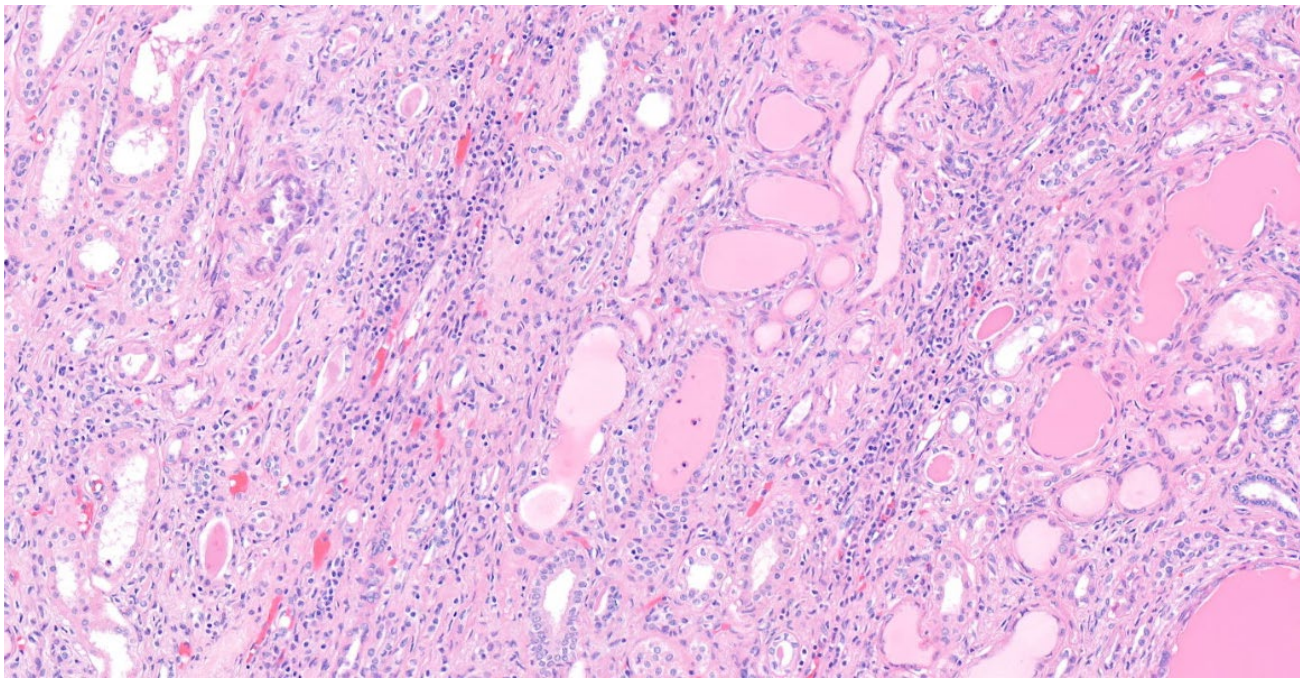


04a. Scigen 7110 at 40x 1A

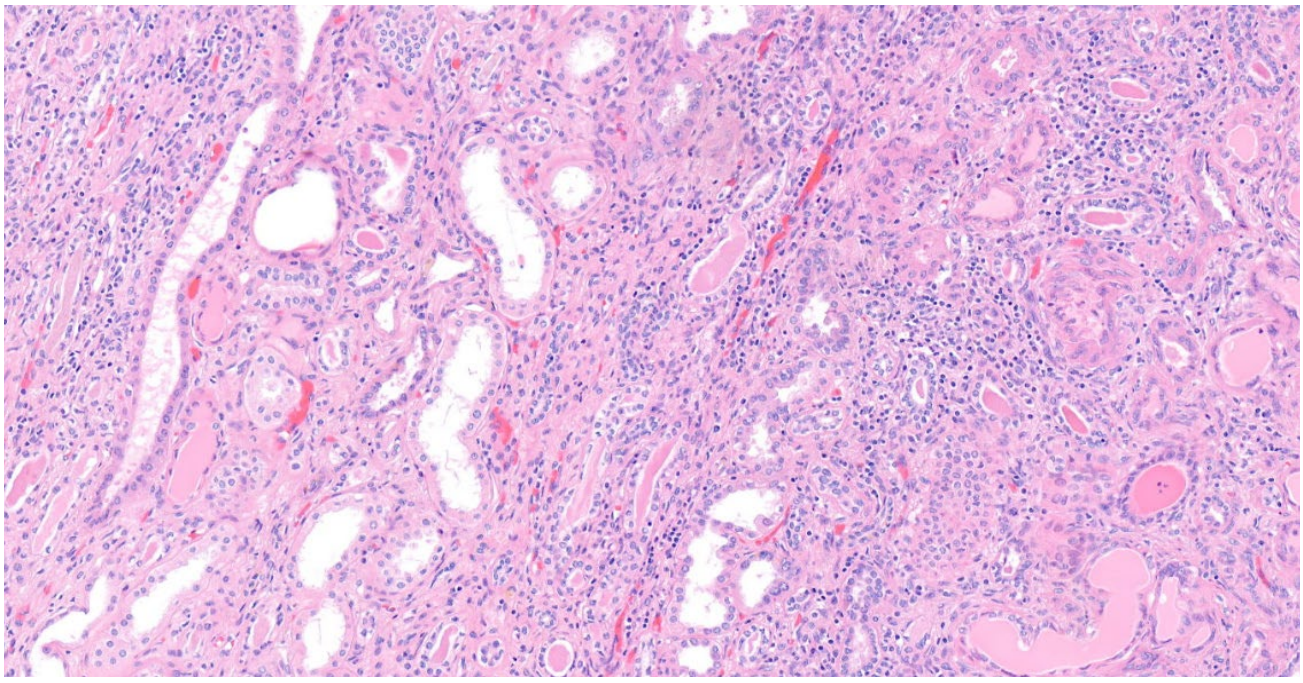


04b. Scigen 7110 at 40x 1B

Repeatability Slide Study

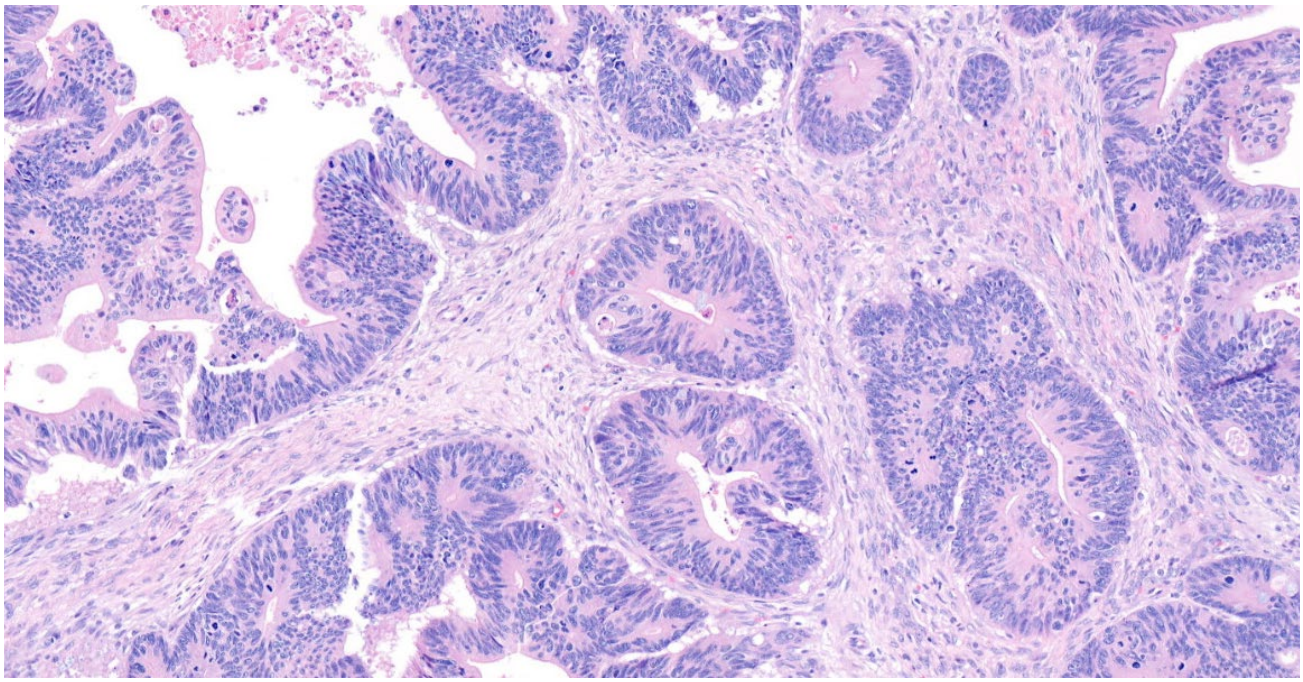


05a. Scigen 7110 at 10x 1A

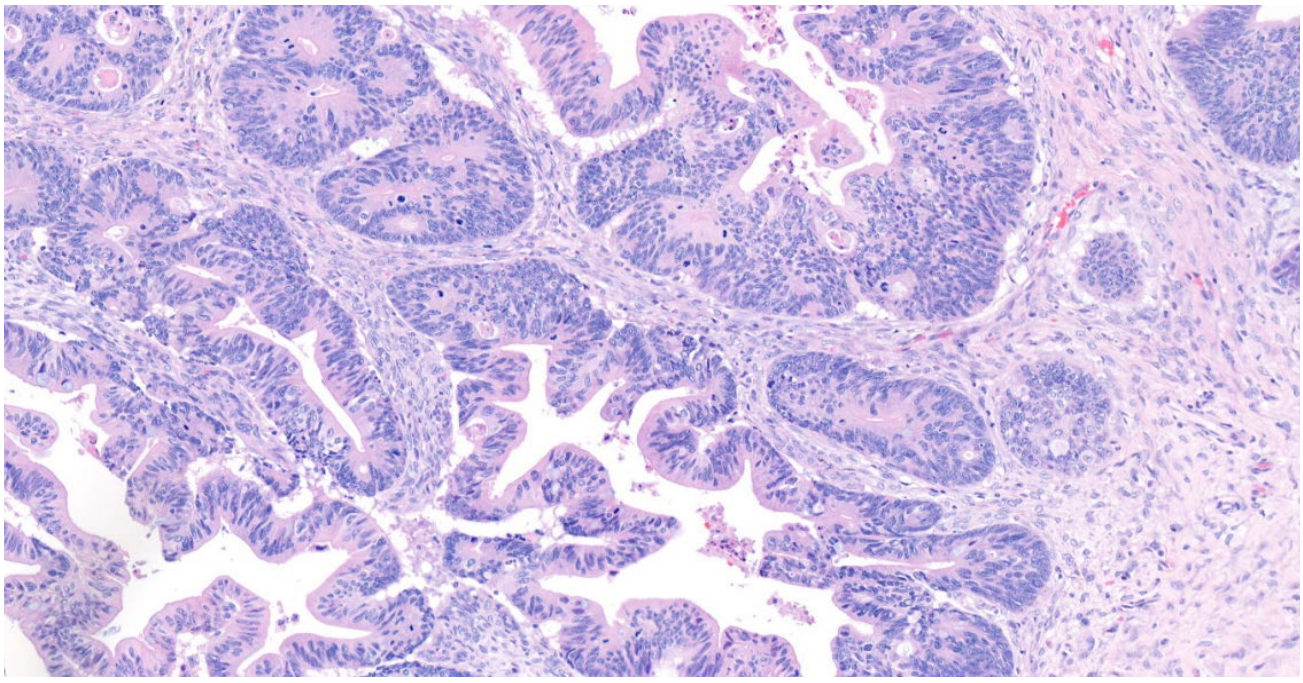


05b. Scigen 7110 at 10x 1B

Repeatability Slide Study



06a. Scigen 7110 at 10x 1A



06a. Scigen 7110 at 10x 1B

Scigen® Premium Staining System

Scigen® Stains have been designed to be used individually or together as a holistic staining system. Carefully formulated with pharmaceutical grade materials while adhering to the highest quality standard, ISO 13485, we are able to provide our customers with unparalleled repeatability from batch to batch and proven consistent, reliable results.

IN VITRO DIAGNOSTIC USE.
FOR USE IN HISTOLOGICAL AND CYTOLOGICAL STAINING PROCEDURES.

HEMATOXYLIN

7110	23-730-561	Hematoxylin	1 Liter	1 unit / ea
7111	23-730-607	Modified Harris Hematoxylin	1 Liter	4 units / cs

EOSIN-Y

7115	23-730-609	Eosin-Y alcoholic	1 Liter	4 units / cs

BLUING REAGENT

7121	23-730-612	Bluing Reagent	1 Gallon	1 unit / ea

DIFFERENTIATOR

7119	23-730-614	Clear Contrast Clarifier	1 Gallon	1 unit / ea

STAIN-AWAY™ WIPES

4275	23-730-626	Stain Removing Wipes	60 Wipes	1 unit / ea