



SARS-CoV-2

Immunohistochemistry

Purpose	<i>Demonstrate infection with SARS-CoV-2 virus in human tissue from autopsy</i>
Indications	<i>Postmortem diagnosis of clinically suspected infection, when nasopharyngeal swab screening results are not available, or a “false negative” screening result is suspect in the setting of suspicious pathological findings.</i>
Specimen type(s)	<i>Formalin-fixed lung Paraffin block of lung tissue Recuts of lung tissue on positively charged slides</i>
Specimen preparation	<i>Formalin-fixed lung tissue at autopsy; ideally, perfuse lungs with formalin via airways prior to dissection</i> <i>Prepare paraffin blocks as per industry standard techniques</i> <i>Prepare one (1) H&E-stained section from each lung block, and two (2) unstained sections from each lung block – all on positively charged slides</i>
Specimen collection / handling	<i>Complete NAAG Pathology Labs Services Request Form, send via email to consults@naagpathology.com</i> <i>Submit tissue, blocks and/or slides according to the NAAG Pathology Labs PC Recommendations for Shipping Specimens document</i>

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Specimen rejection criteria

Unfixed tissue

Broken slides

Non-standard size of slides or blocks (i.e. whole mounts)

Immunogen detail

This polyclonal antibody was developed by immunizing rabbit with a synthetic peptide corresponding to amino acids 399-411 from the N (SARS nucleocapsid) for the human SARS coronavirus (Genbank accession # YP_009724397.2)

Specificity

Dot blot results using recombinant proteins for cross-reactivity testing revealed high reactivity to SARS-CoV-2 nucleocapsid protein and low/no reactivity towards H1N1. No cross-reactivity was observed with influenza A virus, influenza B virus, respiratory syncytial virus, parainfluenza virus type 3, human coronavirus (HCoV) or MERS-CoV in PCR-confirmed tissue samples.

Limitations

Immunoreactivity may be impacted by tissue decomposition

The age of the paraffin block can affect immunoreactivity

Quality assurance

This test was validated using industry standard techniques for immunohistochemistry laboratories

Control slides

If positive and negative control slides are not included with the test subject slide(s), representative positive and negative control photomicrographs are available upon request from consults@naagpathology.com

Test classification

This test was developed and its performance characteristics determined by NAAG Pathology Labs PC in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration (FDA). Use of the analyte specific reagents in this test does not require FDA approval.

Selected citations

Martines, R. B., Ritter, J. M., Matkovic, E., Gary, J., Bollweg, B. C., Bullock, H., . . . Group, C.-P. W. (2020). Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease, United States. *Emerg Infect Dis*, 26(9), 2005-2015. doi:10.3201/eid2609.202095

Rapkiewicz, A. V., Mai, X., Carsons, S. E., Pittaluga, S., Kleiner, D. E., Berger, J. S., . . . Reynolds, H. R. (2020). Megakaryocytes and platelet-fibrin thrombi characterize multi-organ thrombosis at autopsy in COVID-19: A case series. *EClinicalMedicine*, 24, 100434. doi:10.1016/j.eclinm.2020.100434

Schaefer, I. M., Padera, R. F., Solomon, I. H., Kanjilal, S., Hammer, M. M., Hornick, J. L., & Sholl, L. M. (2020). In situ detection of SARS-CoV-2 in lungs and airways of patients with COVID-19. *Mod Pathol*. doi:10.1038/s41379-020-0595-z

Hecht, J. L., Quade, B., Deshpande, V., Mino-Kenudson, M., Ting, D. T., Desai, N., . . . Roberts, D. J. (2020). SARS-CoV-2 can infect the placenta and is not associated with specific placental histopathology: a series of 19 placentas from COVID-19-positive mothers. *Mod Pathol*. doi:10.1038/s41379-020-0639-4

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