



**Department
of Health**

**Wadsworth
Center**

COVID-19 testing in New York's public health laboratory.

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Disclaimer

I have no relationship, fiscal or otherwise, with any of the companies or products I will mention by name.

Molecular assays – FDA approved

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

- There 37 PCR-based assays for SARS-CoV-2 that have been approved under the FDA's EUA process
- The majority of these are assays that should be used in a high-complexity laboratory
- Three are waived assays
- There are many supply chain issues for reagents

Molecular Assays at Wadsworth

FDA EUA- approved

- New York SARS-CoV-2 Real-time RT-PCR
- Cepheid Xpert Xpress SARS-CoV-2 test
- NeuMoDx SARS-CoV-2 Assay

Importance of using multiple platforms

Which specimen?

- Nasopharyngeal - gold standard
- Nasal, mid-nasal turbinate
- Oropharyngeal
- Saliva

NYS DoH Study

226 usable specimens/results

Total pos in any specimen type = 93

NPS pos = 91

NS pos = 81

Saliva pos = 81

- If we tested NP only: 91/93 pos. 2/93 (2%) would be missed
- If we tested NS only: 81/93 pos. 12/93 (13%) would be missed
- If we tested saliva only : 81/93 pos. 12/93 (13%) would be missed
- **If we tested NS + Saliva: 88/93 pos. 5/93 (5%) would be missed**



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Serology assays - FDA

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

- Antibody-based assays are being developed at multiple labs but are not yet widely available
- **Four** assays are FDA approved for use in moderate or high complexity laboratories
- There are over 70 serology assays listed on the FDA website

These are NOT FDA reviewed, nor approved.

Must be used with a disclaimer

Assays at Wadsworth

CLEP- approved

- Microsphere Immunoassay (MIA) using venous blood (FDA EUA-application submitted)
- MIA using bloodspots as sample source
- Plaque reduction neutralization assay

Importance of interpretation

Positive and negative predictive value

$$PPV = TP / (TP + FP)$$

Translation: if you get a positive result, what is the likelihood that it is correct?

$$NPV = TN / (TN + FN)$$

Translation: if you get a negative result, what is the likelihood that it is correct?

PPV and NPV are dependent on the prevalence of disease, as well as the sensitivity and specificity of test being used.

How good are the tests?

Things to consider in the COVID-19 pandemic

- Sensitivity – impact of false negatives
- Specificity – impact of cross-reactivity
- Reproducibility
- Timing of specimen collection
- Disease state
- When are rapid test systems appropriate

Interpretation of serology assays?

Yes

- Seroprevalence studies
- Evidence of prior infection

More study needed

- Return to work without PPE
- Immune

Seroprevalence studies: Planning for the future

Why are they important?

What knowledge do we gain?

How will they help us plan?

NIH begins study to quantify undetected cases of coronavirus infection

<https://www.nih.gov/news-events/news-releases/nih-begins-study-quantify-undetected-cases-coronavirus-infection>

New COVID-19 Antibody Pilot Testing Begins Friday Across LA County

<https://losangeles.cbslocal.com/2020/04/10/new-covid-19-antibody-pilot-testing-begins-friday-across-la-county/>