QPS // SARS-CoV-2

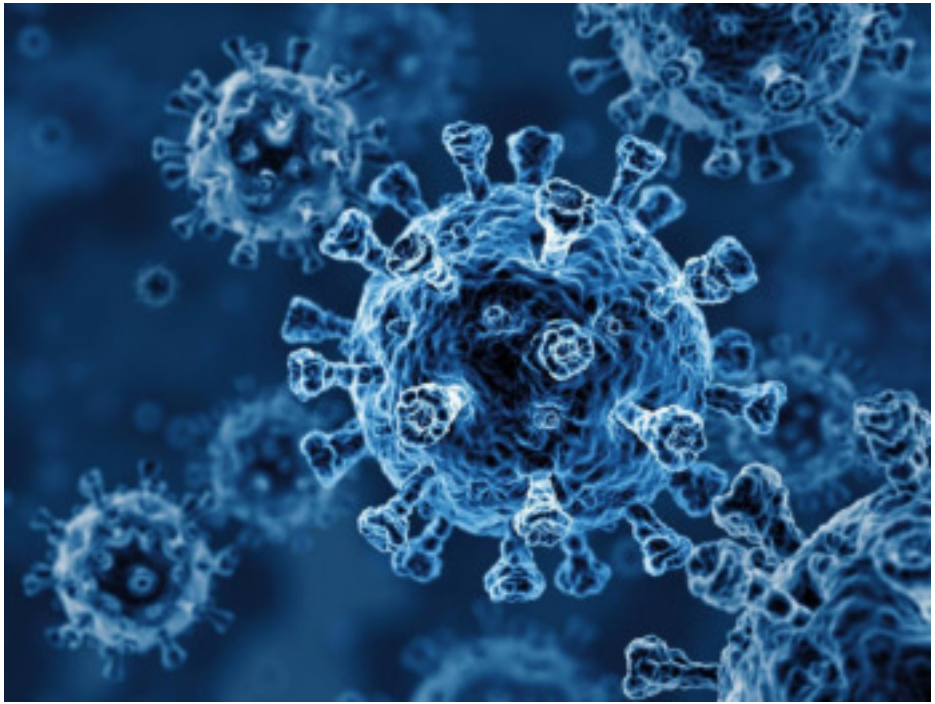
CUSTOM-BUILT RESEARCH // TESTING AT THE READY

AUGUST 2020

The Global Pandemic: A Call to Arms

- QPS is supporting sponsored clinical trials using our subject recruitment services and clinics distributed globally, then handling molecular analysis in our GLP and GCP testing laboratories.

- Also, we recognize that testing for the SARS-Cov-2 virus and the state of human infection, is the first line of defense and we want to contribute our skills and expertise.

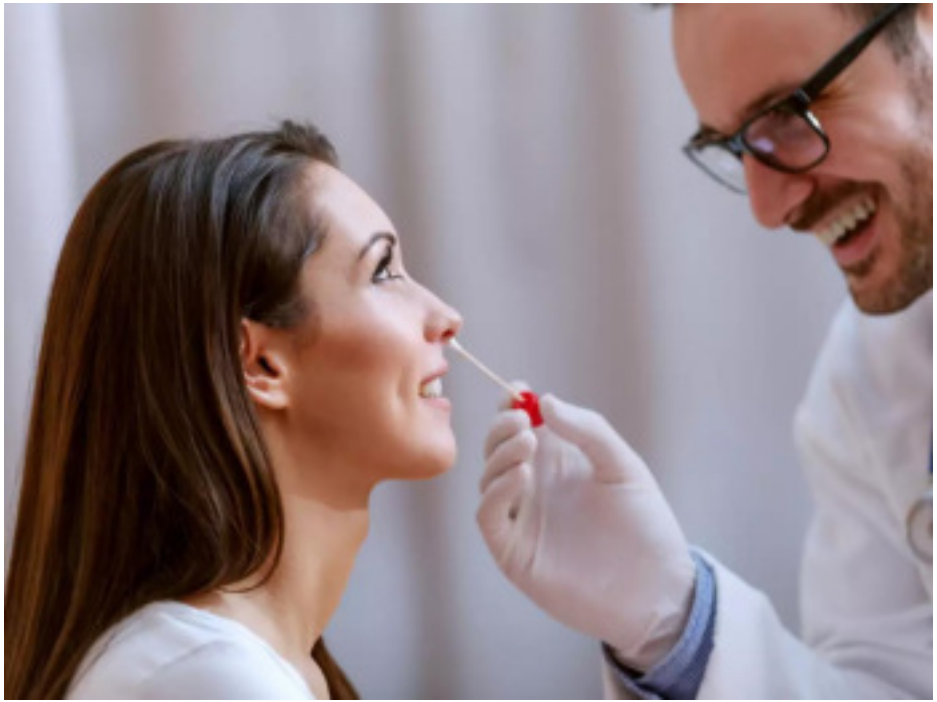


QPS SARS-CoV-2 Molecular Tests

- QPS has four molecular tests for COVID-19 in place or in development. They are:
- In Place
  - The SARS-CoV-2 Diagnostic test (USA only)
  - A Serologic test for SARS-CoV-2 antibodies (USA and NL)
- In Development (USA only)
  - A Quantitative SARS-CoV-2 genomic test
  - An Idiopathic upper-respiratory infection test

The QPS SARS-CoV-2 Diagnostic Test

- Thermo-Fisher Scientific, TaqPath COVID-19 Multiplex Diagnostic Solution
- FDA EUA authorized
- The test is multiplexed
- The test recapitulates the original CDC design
- This is a qualitative test
- The limit of detection = 50 copies/test
- Our preferred collection method is the gold standard:
  - The nasopharyngeal swab or NP swab.
  - The Oropharyngeal swab collection (OP swab), the so-called “strep-test” collection.



The QPS SARS-CoV-2 Diagnostic Test

- The testing is performed in our Newark, Delaware facility by highly trained staff.
- The process is highly automated
- GCP or CLIA governance
- CLIA implementation includes:
  - Result reporting 24-hours after receipt of shipment, typically 48 hours after collection and we are approved to test CLIA samples from all 50 States.
  - Documentation to the authorizing medical professional, the subject, when requested, and mandatory reporting to State authorities in which the subject resides.

The QPS SARS-CoV-2 Diagnostic Test Scenarios

- Subject or patient samples that are part of Clinical trial and used for inclusion or exclusion.
  - This is done to CLIA and contracted by the Study Sponsor.
- Samples from Clinic staff, to assure that Clinical Test conditions do not interfere with Study execution.
  - This is done to CLIA and contracted by either the Clinic or the Study Sponsor.
- Testing of samples from non-Clinical commercial sites in support of Workplace testing for staff surveillance and/or contact tracing that is defined and mandated by commercial leadership.
  - This is also done to CLIA.

The QPS SARS-CoV-2 Diagnostic Test Scenarios

- So-called Workplace Diagnostic testing is interesting as collections are performed in a non-clinical environment.
- QPS facilitates the process by providing necessary add-on services, these services include:
  - Online HIPPA-compliant digital platform for Protected Health Information (PHI) Collection
  - Approved Test requisitions and consultation, as needed, with board-certified physicians for those with positive results
  - NP swab kit availability and shipment to the collection site
  - On-site sample collection by trained nurses

Use of the SARS-CoV-2 Diagnostic Test

The utility of the Diagnostic test is two-fold:

- Identifying infected persons as soon as possible so they can self-quarantine and limit spread of the contagion.
- Shortening the quarantine of previously infected or potentially infected persons. CDC guidance lists 10-14 days of self-quarantine, depending upon exposure type.
  - Two Diagnostic test Negative results separated by 24 hours or more, releases the subject from quarantine.

The QPS Serologic Test for SARS-CoV-2 Antibodies

- A proprietary test on the ELISA platform
- Tuned to detect circulating IgG antibodies to the receptor binding domain of the spike protein of SARS-CoV-2
- Sensitivity of the assay, calculated as the Percent Positive Agreement (PPA), was found to be 92.4%
- Specificity of the assay, calculated as the Negative Percent Agreement (NPA), was found to be 98.0%
- The qualitative IgG serologic test has been submitted to the FDA for EUA approval
- The qualitative IgG serologic test is available to GCP at this time

Use of the Serologic Test for SARS-CoV-2 Antibodies

- IgG sero-positivity reaches a maximum among infected persons about 14 days after infection.
- It is an indicator of prior SARS-CoV-2 infection and is very specific. It is not an indicator of current infection.
- The state of our understanding at this time is that SARS-Cov-2 sero-positivity follows infection.
- This protected state has been shown to last for three months after the initial infection and possibly longer.

Scenarios for the Use of the Serologic Test

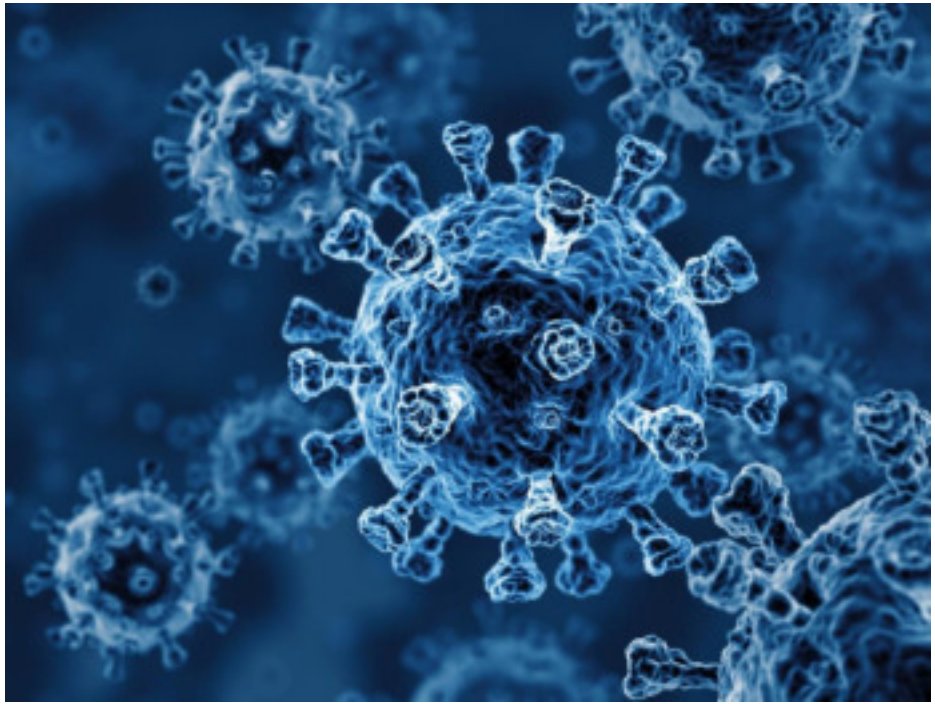
- Taken together, the test can be used for:
- Subject or patient samples that are part of Clinical trial and used for inclusion or exclusion.
  - This is done to CLIA and contracted by the Study Sponsor.
- Characterizing or better understanding a clinical trial patient population or to assess the impact of COVID-19 on study results.
  - This is likely a GCP endeavor.
- Testing of samples from non-Clinical commercial sites in support of Workplace testing for staff perhaps as part of a return to work initiative that is defined and mandated by commercial leadership…with concerns.
  - This is also done to CLIA.

Two Tests in Development

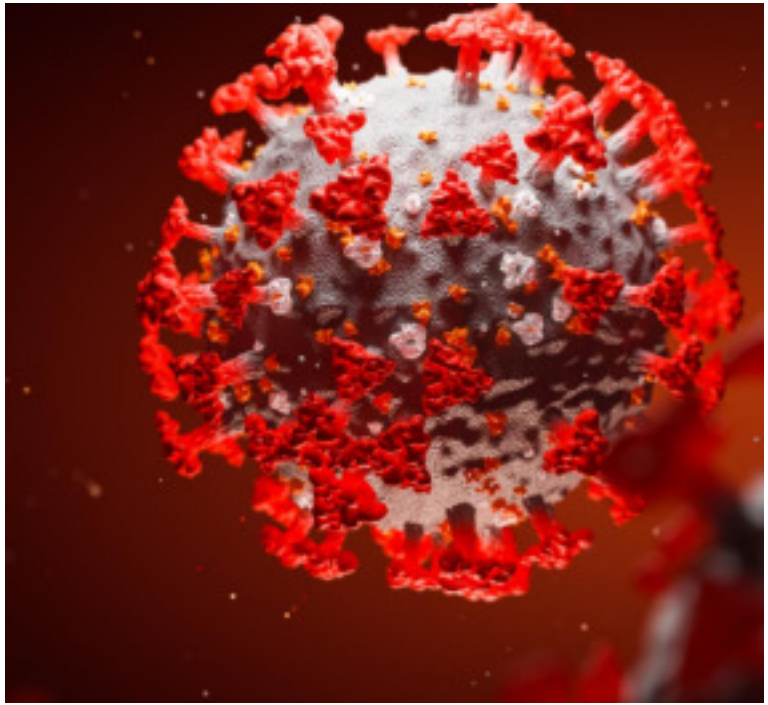
- A Quantitative SARS-CoV-2 genomic test.
  - Like the sero-test, this is a proprietary test designed and built by the QPS Team that engineers all our custom QPCR assays.
  - The intent is to provide a test for viral load studies as part of clinical trials for COVID-19 therapies. It will be offered to GCP.
- An Idiopathic upper-respiratory infection test.
  - This is a qualitative, multiplex QPCR for twenty plus viruses and bacteria common during flu season including Flu, SARS-CoV-2 and the common coronaviruses
  - The intent is to separate SARS-Cov-2 patents and anxiety from the regular repertoire of cold and flu agents this fall.

In Conclusion

- QPS has adjusted and improved processes to ensure our staff stay healthy and our labs remain operating at 100%
- We have developed and are running multiple SARS-COV-2 test types, in support of the global efforts to control the pandemic
  - Molecular test for SARS-CoV-2 viral RNA (available in the USA only)
  - IgG Serologic test for SARS-CoV-2 antibodies (available in the USA and NL)
- You can also find additional information on the coronavirus page of our website, www.qps.com/coronavirus
- You can review our thoughts and insights on our blog page www.qps.com/news/blog



QPS Business Development Contacts



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