QPS // SARS-CoV-2
CUSTOM-BUILT RESEARCH // TESTING AT THE READY
AUGUST 2020
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 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 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.
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
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.
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.
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