

If calling please ask for:

Direct line: [REDACTED]

Email: [REDACTED]

Our ref: [REDACTED]

22nd June 2020

[REDACTED]
AlphaBiolabs
14 Webster Court
Carina Park
Warrington
WA5 8WD

Dear [REDACTED]

I am writing to thank you for your generous donation of NADAL IgM/IgG POC test kits to Oldham in order to support our response to the COVID19 Outbreak.

I can confirm that we have now finished our local evaluation of these tests. This involved assessing 180 of the test kits using blood from local people who had their COVID19 antigen status proven by robust PCR antigen testing. A further 40 tests were used in the community to assess ease of use and supervision via video consultation.

For both positive and negative tests there was a very high correlation and we have concluded that these tests are now 'Fit for use'

We will be using them initially as a screening test for our entire workforce with particular focus on those who had symptoms or exposure at least 21 days ago. We intend to feed this data into national reporting to aid our PHE and Academic colleagues in building a better picture of how COVID19 is affecting the UK population.

As we approach winter you will understand how useful these tests will become in helping us distinguish COVID19 from usual 'cold' viral symptoms.

We particularly appreciate that these are POC tests which will allow us to offer testing to the many people for whom venesection is not a preferred option.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
w. [REDACTED]
t. [REDACTED]



A formal report of the evaluation is being written up by our Hospital colleagues but they have agreed I can share their initial findings.

The 180 tests showed a very good specificity*

98.8% for IgM and 100% for IgG

When looking at the tests sensitivity it was observed that antibodies developed at different rates in different subjects over time.

By day 15 40% had IgM and 27% had IgG. By day 21, 100% of tested PCR positive subjects had IgM antibodies and 85% had IgG.

Currently our only Validated antibody test is a hospital based process accessed by venesection that gives us a single IgG reading without a formal titre. Thanks to your generous donation we now have an alternative to carry out widespread workforce screening and this will have significant positive impact on our ability to offer healthcare and social care services to the population of Oldham and beyond.

The above data has let us calculate the test's 'Predictive value' as >80% (remember the lag in onset of developing antibodies). This is one of the accepted benchmarks to pass in order for a test to be evaluated as 'Fit for use'

Many thanks again.

[REDACTED]

Kind regards

Yours sincerely

[REDACTED]

Dr [REDACTED]

[REDACTED]

NHS Oldham CCG

