Features

- Reagent kits for both IgG and IgM tests for SARS-CoV-2 can provide comprehensive solution for the detection of COVID-19.

- With strong social responsibility and professional R&D team, we made independent development of raw materials and stable supply for new assays within 1 month.

- Anti-interference to Legionella pneumococcal, mycoplasma pneumonia, chlamydia pneumonia, adenoviruses, respiratory syncytial viruses, influenza A, influenza B and para influenzas 1, 2 and 3, etc.

- Up to 1200 T/H can be achieved by our iFlash series CLIA analyzers (iFlash 1800: 120 T/H; iFlash 3000: 300 T/H; iModule: up to 1200 T/H).

Based on 1216 sample evaluations in 16 Chinese Class A hospitals (dated before February 25, 2020), we achieved initial evaluation data as below:

- Average Sensitivity for IgM: >90% (clinical diagnosed patients)
- Average Specificity for IgM: >95% (negative patients)
- Average Sensitivity for IgG: >85% (clinical diagnosed patients)
- Average Specificity for IgG: >95% (negative patients)

Assay Information

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>C86095G</td>
<td>iFlash SARS-CoV-2 IgG</td>
<td>2×50T</td>
</tr>
<tr>
<td>C86095M</td>
<td>iFlash SARS-CoV-2 IgM</td>
<td>2×50T</td>
</tr>
</tbody>
</table>
The ongoing outbreak of COVID-19 (coronavirus disease 2019), caused by SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2), started in December 2019. It was first identified in Wuhan, the capital of Hubei Province, China.

SARS-CoV-2 is a positive-sense single-stranded RNA virus, and it is contagious in humans. From a taxonomic perspective, SARS-CoV-2 is classified as a strain of the species named severe acute respiratory syndrome-related Coronavirus (or SARS-CoV).

SARS-CoV-2 IgM/IgG Detection

SARS-CoV-2 produces specific antibodies against pathogens after first infection in the human body. The earliest antibody produced is IgM, which is secreted directly by the B-cell surface receptor. The B cells that produce IgM enter the lymph nodes, receive stimulation from T cells and antigen-carrying cells at the center of the occurrence, further mature, differentiate into plasma cells, and produce a large amount of IgG.

Based on the above paper published in Nature on January 29, 2020 (authors are from China Wuhan local medical hospitals and China CDC), based on two preliminary IgM and IgG ELISA kits, we can find that:

- IgM titer increased rapidly in the first few days, and then it started to decline.
- IgG titer increased steadily from the first day and kept at high level for a long time.
- For 5 positive patients around 20 days after disease onset, all of them showed IgG positive, 3 of them showed IgM positive, as comparison, no healthy people showed IgG or IgM positive. Cutoff was set to be 0.2 for IgM and 0.3 for IgG.

WHO Interim Guidance (17 January 2020)

Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases

Interpretations (for reference)

<table>
<thead>
<tr>
<th>SARS-CoV-2</th>
<th>IgM</th>
<th>IgG</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAT Positive</td>
<td>At least one positive</td>
<td>Confirmed diagnosis, YHLO CLIA assays can be used for treatment monitor later.</td>
<td></td>
</tr>
<tr>
<td>All negative</td>
<td>Confirmed diagnosis, maybe in window period for immunoassay (recommend to test IgG/IgM 2 weeks later).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NAT Negative

<table>
<thead>
<tr>
<th>IgM</th>
<th>IgG</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Nucleic acid and antibody negative, rule out infection</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>Doubtful results, it is recommended to test NAT again with low respiratory specimen for confirmation of NAT results. Some NAT negative patients were confirmed by positive antibodies results, together with the aid of CT scanning results for lung.</td>
</tr>
</tbody>
</table>

Chinese Experts Opinions