PathLab SERVICES

COVID-19 SARS CoV-2 "CLINICAL UPDATE" June 8th, 2020

Due to COVID-19 pandemic, PathLab Services took necessary steps to establish SARS-CoV-2/COVID-19 testing that is authorized by FDA under an Emergency Use Authorization (EUA):

- Active Viral Detection SARS CoV-2 Qualitative RT-PCR
- Antibodies Detection for SARS CoV-2 IgG/IgM
  - Venous blood draw collection (Serum/Plasma) on DIAZYME DZ-Lite kit with DZ-lite 3000
  - Finger prick IgG/IgM testing for drive-up sites on ORIENTGENE Bio confirm testing cassettes

Test Name:	**SARS-CoV-2 RNA, QUALITATIVE RT-PCR**
Methodology:	Real-Time (RT) Reverse Transcriptase Polymerase Chain Reaction (rPCR)
Testing Platform:	Applied biosystems Quant Studio 12k/Thermofisher/Taqpath COVID-19
Testing Sensitivity:	100% at 10 GCE/reaction
Testing Specificity:	100% specific to SARS CoV-2 RNA
Collection Sources:	Nasal swab (N), nasopharyngeal swab (NP) or oropharyngeal (throat)
Collection Swabs:	Flocked, rayon, or polyester fiber swabs. Select swabs with serrated shafts
Transport Media:	(1) Multi microbe media (M4, M4RT, M5, M6) (2) VTM media "green-cap" tube or equivalent (UTM)
Transport Temperature:	Specimens must be kept cool - If transported ≤72 h, keep at 4oC - If transported >72 h, keep at -70oC (ship on dry ice)
Specimen Stability:	Stored at 4oC for up to one week; long term storage at -20oC in non-frost freezer acceptable
Reference Range(s)	Not Detected

Test Name:	**SARS CoV-2 IgG / IgM Antibodies**
Methodology:	Fully Automated Chemiluminescence Immunoassay Instrument
Testing Platform:	Diazyme DZ-Lite SARS-CoV-2 IgG/IgM CLIA Kit with the DZ-lite 3000 Plus
Testing Sensitivity:	89.89% When used in combination IgG/IgM
Testing Specificity:	96.50% When used in combination IgG/IgM
Collection Sources:	Venous Blood Draw in SST "serum" or K2-EDTA, K3-EDTA, Na2 –EDTA "Plasma"
Transport Temperature:	Transported Separated serum/Plasma from blood ASAP to lab at 2-8^{o}C
Specimen Stability:	Stored at 2-8^{o}C for up to 3 days; long term storage at -20^{o}C freezer acceptable
Reference Range(s)	Non-Reactive

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