BIOGENIX

POLICY AND PROCEDURE ON ADVISORY SERVICES

	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	SHIVARAJ NAIK	INFECTION CONTROL OFFICER		01/07/2020
Reviewed by	DR. BHAGYASHREE THAKRE	LABORATORY DIRECTOR DEPUTY		01/07/2020
Reviewed & Approved by	DR. SALLY ABDULLA IBRAHIM	LABORATORY DIRECTOR		01/07/2020

1. TABLE OF CONTENT

2 REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3 REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4 POLICY STATEMENT:

4.1 Biogenix laboratory offers advisory services and consultations to clients, clinician and/or referring facility based on the laboratory results generated and service offered.

5 PURPOSE

5.1 This procedure explains the advisory services offered by Biogenix laboratory to the clients, clinician and/or referring facility.

6 SCOPE

6.1 The scope of this policy extends to all the advisory services offered by lab personnel.

7 DEFINITIONS

7.1 N/A.

8 ACRONYMS

8.1 PCR – Polymerase Chain Reaction

9 RESPONSIBILITIES

9.1 Laboratory Director

9.2 Pathologist

9.3 Lab Admin Staff/ Coordinators

10 PROCEDURE

10.1 Biogenix laboratory provides advisory services to the clients and referring facility. The responsible person for providing advisory services is the laboratory director, pathologists and lab coordinators.

10.2 The advisory services include consultation on full range of available tests, test instructions, special instructions for specific tests like timed collections, the turnaround time and method of release of reports.

10.3 The following means are used for providing advisory services.

10.3.1 **Footnotes/comments/remarks added as part of reports** - Whenever the Lab Director sees an opportunity to provide more information or explanation about the patient test/result, it may be done in the form of footnote/remarks/comments in the final report. Some report formats (eg. Covid 19 PCR, Anti HbS & SARS-CoV-2 IgG) have comments added as a default.

Covid 19 PCR Report
Comment: This is a qualitative real time PCR technique for the identification of COVID19 virus Orf1ab gene. Sensitivity is 100 copies/ml Specificity: no cross reaction with other viruses. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions Negative results must be combined with clinical observations, patient history, and epidemiological information SARS-CoV-2 is a new type of coronavirus discovered in 2019. It belongs to the beta coronavirus genus and is the pathogen of the new coronavirus disease (COVID-19) in 2019. The virus is highly contagious, with an incubation period of 1-14 days. Asymptomatic infection may also become the source of infection. Spreading of respiratory droplets and close contact transmission are the main routes of transmission. The virus is often found in respiratory tract samples of patients with COVID-19, and it has been reported that it is also detected in stool and urine.
SARS-CoV-2 IgG report

Comment:

The SARS-CoV-2 IgG assay is designed to detect immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-CoV-2 in serum and plasma from patients with signs and symptoms of infection who are suspected of coronavirus disease (COVID-19) or in serum and plasma of subjects that may have been infected by SARS-CoV-2.

Results suggest recent or prior infection with SARS-CoV-2. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. Protective immunity cannot be inferred based on these results. Infrequently, false positive results may be due to prior infection with other human coronaviruses. Serologic results should not be used as the sole basis to diagnose or exclude recent or past SARS-CoV-2 infection.

Anti HbS Report

Interpretation: Anti-HBs assays are used to monitor the success of hepatitis B vaccination and their presence has been shown to be important in protection against Hepatitis B virus infection.

Anti-HBs assays are also used to monitor the state of convalescence and recovery. The presence of anti-HBs antibodies after acute HBV infection and loss of hepatitis B surface antigen (HbsAg) can be a useful indicator of disease resolution.

Based on the World Health Organization recommendation, an Anti-HBs concentration ≥ 10 mIU/mL is regarded as being protective against Hepatitis B viral infection.

Comment:
For diagnostic purposes, test results should be used in conjunction with patient's medical history and other hepatitis markers for acute, chronic or convalescent phases of infection.

10.3.2 **Electronic communications through email:** Whenever a user seeks advisory services of lab, Lab Director, pathologist and lab coordinator offer advisory services through email through official email ID (g42lab@g42.ai) provided for the communication.

10.4 Advisory services on the limitations of examinations services:

10.4.1 Advisory on limitation of examination procedures pertaining to effect of various factors like insufficient sample, hemolysis, lipemia or hyperbilirubinemia are conveyed to users through comments in final reports.

10.4.2 Also advice is given to clinician or referring facility regarding limits of detection of analyte in reference to linearity of the analyzers. These advices can be in either form, oral (one to one discussion) or as comments on reports.

11 CROSS REFERENCE:

11.1 ISO 15189 Third Edition 2012-11-01 corrected version 2014-08-15, Medical laboratories- Requirements for quality and Competence

11.2 HAAD clinical laboratory standards version I.

12 RELEVANT DOCUMENTS & RECORDS:

12.1 BG/PP/GEN/002 Policy Procedure for General Communication.