GENERAL DIAGNOSTICS INTERNATIONAL (P) LTD.

RPT House, Plot No. - 06, Sector - 24, Turbhe, Navi Mumbai-400705, India. Customer Support : +91 98717 15111



Client Name:





Name: Mr. Sanchit Agrawal Age/Gender: 24 Year(s) 0 Months(s) 0 Day(s)/Male

Referred By: Self

Collection Date: 20-07-2023 17:22:00 **Report Release Date:** 22-07-2023 15:53:32

1	No. Investigation	Observed Value	Unit	Biological Ref. Interval				
Qu	Quantiferon -TB Gold; Gamma Interferon							
1	Conc of background control tube(N)	0.011	IU/ml					
2	Conc of testing culture tube(T)	0.011	IU/ml					
3	T-N	0.00	IU/ml					
4	Final Result	Negative						

Interpretation

Method: Interferon Gamma Release Assay (IGRA) Chemiluminescent microparticle immunoassay(CLIA Microparticles).

CRITERIA FOR INTERPRETATION:

N(IU/mL)	T Minus N (IU/mL)	Result	Interpretation
<=10.0	<0.438	Negative	Tuberculosis may not infect T cell.
<=10.0	>=0.438 and <25% N	Negative	Tuberculosis may not infect T cell.
<=10.0	>=0.438 and >=25% N	Positive	Tuberculosis may infect T cell.
>10.0	<0.438	Indeterminate	Likelihood of Tuberculosis infecting T cell is can not be determinated.
>10.0	>=0.438 and <25% N	Indeterminate	Likelihood of Tuberculosis infecting T cell is can not be determinated.
>10.0	Any	Indeterminate	Likelihood of Tuberculosis infecting T cell is can not be determinated.

Note: N: Test value of negative control culture hole;T: Test value of testing culture hole.

Test Description



CRM No :5981606

Sample Recd. Time: 21-07-2023 05:13 Report Time: 22-07-2023 15:53 Patient Name: Mr. Sanchit Agrawal

Patient ID: 5981606



Authorized Signatory Dr. Anju Dhar MD (Microbiologist)



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Interpretation

- Interferon- gamma release assay (Quantiferon TB) is an in vitro, indirect method for documenting cell mediated immune response using a peptide cocktail of ESAT-6, CFP-10 & TB7.7 protein antigens that are associated with M. tuberculosis complex infections. The interferon-Gamma released in plasma by the stimulated white cells (effector T cells) is estimated by ELISA. The assay is thus dependent on host immune status.
- The pooled sensitivity & specificity of the test for diagnosing M. tuberculosis infection in developing countries is 78 to 83% & 98 to 100% respectively

Note: This test is used as aid in the diagnosis of latent & active tuberculosis but does not distinguish between the two forms of the disease A positive result supports the diagnosis of the tuberculosis.

Diagnostic test recommended by WHO: Xpert MTB/RIF (TB PCR Test).

Interpretation

- Latent TB infection (LTBI) is a noncommunicable, asymptomatic condition with a positive IGRA or tuberculin skin test but no clinical, radiological orbacteriological evidence of active disease & can persists for many years. LTBI has a risk to progress to tuberculosis disease, in about 5-10% of immunocompetent hosts and this risk increases with immunodeficiency..
- Management decisions for persons with a positive IGRA result should be based on Risk Assessment findings for the likelihood of M.tuberculosis infection & for progression to tuberculosis disease. IGRA test is not recommended to be used for monitoring the response to treatment.
- IGRA test can be negative in recent contacts of TB exposure (8 10 week false-negative "window" may exist), co-morbid conditions impairing immune function such as HIV infection; immunosuppressive drugs (corticosteroids, TNF-alpha antagonists) ,organ transplantation; hematolymphoid malignancies, Carcinoma in head, neck, or lung; Diabetes; Silicosis and Chronic renal failure.

REFERENCES:

• American CDC (2010) & European CDC (2011) guidelines on TB Quantiferon

End Of Report



CRM No:5981606

Sample Recd. Time: 21-07-2023 05:13 Report Time: 22-07-2023 15:53 Patient Name: Mr. Sanchit Agrawal

Patient ID: 5981606



Authorized Signatory Dr. Anju Dhar MD (Microbiologist)



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Name: Mr. Sanchit Agrawal Age/Gender: 24 Year(s) 0 Months(s) 0 Day(s)/Male

Client Name:

Referred By: Self

Collection Date: 20-07-2023 17:22:00 **Report Release Date:** 21-07-2023 22:37:19

No.	Investigation	Observed Value	Unit	Biological Reference Interval
1	Mumps Virus IgG antibody Serum, Method: CLIA	Positive,191	AU/ml	Negative: < 9.0 Equivocal: 9.0-11.0 Positive: >= 11.0

Interpretation

Mumps virus IgG concentrations below 9.0 AU/mL should be graded negative.

Mumps virus IgG concentrations ranging between 9.0 and 11.0 AU/mL should be graded equivocal

Mumps virus IgG concentrations equal to or above 11.0 AU/mL should be graded positive.

SUMMARY AND EXPLANATION

Mumps is a viral illness caused by a member of the paramyxovirus family and is transmitted by respiratory droplets. It has an incubation period of 14-25 days after which time prodromal symptoms occur and last anywhere from three to five days. After the prodromes, the symptoms of viral infection depend on which organ is affected. The most common presentation is a parotitis, which occurs in 30-40% of patients. Other reported sites of infection are the testes, pancreas, eyes, ovaries, central nervous system, joints, and kidneys. A patient is considered infectious from about three days before the onset of symptoms and up to four days after the start of active parotitis. Infections can be asymptomatic in up to 20% of persons (1). Prior to vaccine availability about 50% of children contracted mumps; however mumps vaccination programs (part of measles, mumps, rubella [MMR] vaccination) have had a marked effect on the incidence of the disease and the complications associated with it (2, 3).

* Test not in the lab scope.

End Of Report

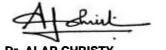


CRM No:5981606

Sample Recd. Time: 21-07-2023 05:09

Report Time: 21-07-2023 22:37 Patient Name: Mr. Sanchit Agrawal

Patient ID: 5981606



Dr. ALAP CHRISTYMBBS, MD, PGDM-HC Head Clinical Chemistry
Reg No.2020/12/6991



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QUALITY POLICY

GENERAL DIAGNOSTICS INTERNATIONAL (P) Ltd. maintains the highest standards of quality control in all aspects of laboratory work. The purpose of our laboratory's Quality Management System is to ensure that:

- Principles of all accreditations, including that of NABL ISO1518:2012 (National Accreditation Board of Laboratories) are adhered for each test in the scope of the accreditation, and beyond.
- Test methods, processes and control mechanisms are timely updated and fully validated to ensure the accuracy and reliability of our test results.

The objectives of our Quality Control system are:

- Use Bar-Coded operations to enable full traceability throughout the sample flow process and to ensure sample handling
 procedures and environmental conditions are managed well and there is no or minimal affect on the results.
- Continually improve the practices of our clients, franchise partners, associate doctors, clinics and hospitals and monitor their training needs. Be proactive in identifying gaps in the processes being followed. Guide them to ensure that the patients are served in the best possible way.
- Report the results with accuracy and clarity in a timely manner. Do a root cause analysis whenever there is a deviation against protocols and find solutions to the identified causes.
- Ensure a continual enhancement, implementation and maintenance of the quality system and seek improvement in the effectiveness of the quality system from experts at regular intervals.
- Meet and exceed expectations with respect to turn-around time, sample collection hygiene & reliability of service.
- Ensure that each test is performed by qualified and trained staff. Provide opportunities to the staff so that they can increase their knowledge and use the same for self and organizational betterment.
- Ensure that the equipment used are best in class, properly maintained and calibrated and where possible, measurements are traceable to recognized standards. Also explore methods which may lead to improvement in equipment performance and methodologies used for conducting tests.
- Enable technology upgrades to achieve higher accuracy and reduced complexities.
- Use internal audits and other checks to ensure the quality system complies with requirements; ensure problems are investigated promptly, root cause(s) established and effective action taken to prevent a recurrence.
- Have a smooth communication mechanism to ensure information is made available as rapidly as possible to those who need it, both internal and external to the organization.
- Monitor, help and support our franchise and service partners to be sensitive on all aspects of service delivery and to ensure quality standards are followed with no exceptions.

CONDITIONS of REPORTING

- It is presumed that the specimen accompanying the TRF (Test Requisition Form where the details of patient are recorded) is of the same patient whose details are there in the TRF
- 02. A test requested might not be performed due to the following reasons (s):
 - $2.1\ In sufficient\ quantity\ of\ specimen\ required\ to\ conduct\ the\ test.$
 - 2.2 Poor quality of the Specimen not meeting the quality criteria (hemolysis of sample/clotted.)
 - $2.3\,Incorrect\,specimen\,type\,as\,required\,to\,conduct\,a\,test.$
- 03. Test(s) may be patly or fully cancelled due to incorrect test code, incorrect name of the test or incorrect type of specimen. A communication shall be made and it is expected that a fresh specimen will be sent to laboratory for analysis of same parameter(s).
- 04. The results of laboratory investigation are dependent on the quality of the specimen as well as the assay procedures/technologies used. All samples collected for tests are required to be prepared, stored, labeled and brought to processing laboratory as per the prescribed guidelines of GENERAL DIAGNOSTICS.
- 05. GENERAL DIAGNOSTICS laboratory cannot be held liable for incorrect results of a sample which deviated from the guidelines issued.
- 06. There can be several factors like sample's unintended exposure to heat or travel through rough terrain which affect the quality of test results. Therefore a 2% chance of error/ deviation in results is a possibility.

- 07. For certain category of tests, the report may carry a "PRELIMINARY" status implying that the results are yet to be reported for one (or more) tests. For example, in the case with certain microbiology tests, a "FINAL" culture, identification or drug susceptibility result might be pending. In such case, the status "RESULT PENDING" will be mentioned on report. The same shall be replaced by the test results whenever it is ready.
- 08. If the collection date or any other details was not stated in the Test Requisition Form, the same will not be printed on the report. In cases where the missing information is mandatory for report generation or meeting accreditation guidelines, the sample shall not be processed at all.
- 09. Tests parameters excluded from the "scope" of NABL accreditation shall be marked by asterisks.
- 10. In case you are not the intended recipient of the report, please immediately inform the same to the issuing entity. Any use, disclosure, copy or distribution of any contents of such report, is unlawful and is strictly prohibited.
- Some test may be referred to other laboratories to provide a wider test menu to the
 patients. The details of the laboratory where the sample was referred to, can be
 obtained from Customer Care department.
- Claims of comparing results against that from a different laboratory shall be looked into only if it was the same sample which was split and sent in same conditions to all laboratories and processed on the same technology.



इस श्रिष्टि का मूल आधार है "बेटी" माता पिता ही नहीं, देश का सम्मान है "बेटी" बेटी बचाओ बे 👺 पढ़ाओ