LIGHTDECK®

COVID-19 TOTAL ANTIBODY TEST

REF 90-00055

For prescription use only.

For in vitro diagnostic use only.

The LightDeck COVID-19 Total Antibody Test has completed the Section IV.D notification process under FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)."

Intended Use

The LightDeck COVID-19 Total Antibody Test is a fluorescence immunoassay performed using the LightDeck T Analyzer, a quantitative instrument designed for use with LightDeck cartridges. The LightDeck COVID-19 Total Antibody Test is for the qualitative detection of total antibodies to SARS-CoV-2 in human serum. The LightDeck COVID-19 Total Antibody Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a that meet requirements to perform high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the LightDeck COVID-19 Total Antibody Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different serology assay.

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Summary

COVID-19 (coronavirus disease 2019) results from infection with SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), a novel human coronavirus first identified in Wuhan, China in December 2019. The disease has a broad spectrum of impact on human health, from no or very mild symptoms to life threatening disease such as severe acute respiratory syndrome (SARS), kidney failure, and death.

Diagnosis of COVID-19 relies primarily on molecular testing for SARS-CoV-2 viral RNA using a swab or saliva sample. Antibody tests like the LightDeck COVID-19 Total Antibody Test detect the presence of an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The test is performed using the LightDeck T Analyzer, a quantitative fluorescence measurement instrument designed to interface with the LightDeck COVID-19 Total Antibody Test cartridge. The LightDeck COVID-19 Total Antibody Test is a fluorescence immunoassay that detects the presence of total antibodies to SARS-CoV-2 (i.e. IgM, IgG, IgA) in human serum.

Assay Principle

The LightDeck COVID-19 Total Antibody Test cartridge contains multiple detection zones printed with Spike RBD recombinant antigen (RBD) and negative and positive controls. After 50 µL of serum is pipetted into the sample inlet, the user inserts the cartridge into the LightDeck T Analyzer. Inside the temperature-controlled analyzer, the sample is automatically mixed with a reagent pellet containing a fluorescently-labeled Spike RBD SARS-CoV-2 recombinant antigen (RBD-F). After mixing, SARS-CoV-2 antibodies in the sample that are specific to Spike RBD will form complexes with the RBD-F labeled antigen. The instrument automatically initiates flow of the sample onto the microarray surface and the antibody-RBD-F complexes (if present) bind to the RBD detection zone using unoccupied antigen binding sites of the antibody. The RBD detection zone signal develops rapidly in the presence of samples with COVID-19 antibodies and is read by the LightDeck software. The internal positive and negative controls in the cartridge are evaluated, and if they are performing within their signal limits, the RBD signal is considered valid.

Components

Components in Kit	90-00055
LightDeck COVID-19 Total Antibody Test	20 per kit
Pipette Tips	22 per kit
Instructions for Use	1 per kit

LightDeck COVID-19 Total Antibody Test cartridges are packaged individually with desiccant and supplied as a 20-pack. Cartridges are single use only.

Pipette tips are supplied in a 22-pack and are compatible with the 50 µL fixed volume pipette supplied with the LightDeck T Analyzer.

Components Required but not Provided	Catalog #
LightDeck T Analyzer	90-00048
50 µL fixed volume pipette	Provided with analyzer *
POS/NEG External Controls	90-00059
Specimen Collection Container	NA
Centrifuge	NA
Biohazard Waste Container	NA

*Replacement fixed volume pipette available from Fisher Scientific (Catalog No.NC1121167)

LightDeck External Controls

COVID-19 Total Antibody Test Positive and Negative Control Kit available from LightDeck Diagnostics (Cat # 90-00059)

Negative Control: Pooled normal human serum collected pre-COVID-19 with COI < 1.00. Supplied frozen.

Positive Control: Human serum spiked with convalescent plasma with COI > 1.00. Supplied frozen.

Preparation of controls: Upon arrival, store frozen at -20°C or lower. Controls can be taken out of the freezer and stored at 2-8°C between use for up to 14 days. Allow frozen vial to come to room temperature and gently mix before testing.

Use of controls: Use the same procedure for dispensing a control as you would for a patient sample, using the 50 µL fixed volume pipette. Always store unused controls at 2-8°C or freeze at -20°C or lower. Avoid repeated freeze-thaw cycles.

Specimen Collection

Human serum is used for this test. Do not attempt to perform the test on a different specimen type or a specimen that contains suspended fibrin or aggregates, or severe hemolysis (hemoglobin content greater than 1000 mg/dL). Icteric samples less than 40 mg/dL bilirubin or samples containing triglycerides less than 1000 mg/dL are acceptable.

If fresh serum is not available, samples can be refrigerated at 2-8°C for one week. If serum samples are frozen, they should be stored at -20°C or lower for no more than three months. Avoid repeated freezing and thawing of samples. Allow frozen specimens to come to room temperature and gently mix before testing.

Storage and Stability

Store LightDeck COVID-19 Total Antibody Test cartridges at 2-8°C until their expiration date. Room temperature storage up to one week is also acceptable.

Precautions and Safety

The LightDeck COVID-19 Total Antibody Test is:

- For prescription use only.
- For in vitro diagnostic use only.
- The LightDeck COVID-19 Total Antibody Test has completed the Section IV.D notification process under FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)."
- This test has not been reviewed by the FDA.

- Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used to diagnose or exclude SARSCoV-2 infection.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Make sure that the test cartridge is not expired (expiration date indicated on the kit box and cartridge pouch).
- The test cartridge is single use and cannot be reused.
- Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
- All the waste and specimens should be treated as biohazardous waste in accordance with local standards.
- Use routine laboratory precautions. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.
- After opening up the test cartridge, it should be used within 10 minutes. It is recommended to allow a cartridge stored at 2-8°C to come to room temperature before opening the pouch to avoid the condensation which might form due to high relative humidity.

Limitations

- Use of the LightDeck COVID-19 Total Antibody Test is limited to laboratory personnel operating under a CLIA high complexity authorization, and who have been trained to operate the test. Not for home use.
- The test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The COI value does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. This test cannot be used as a quantitative test.
- SARS-CoV-2 antibodies may be below detectable levels in patients who tested positive by a diagnostic test or have been exhibiting symptoms for less than 15 days.
- This test should not be used for screening of donated blood.
- Do not use the LightDeck COVID-19 Total Antibody Test with fingerstick samples.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- A positive result may not indicate previous SARS-CoV-2 infection (false positive). Consider other information, including clinical history, local disease prevalence, and possible cross-reactivity from pre-existing antibodies in assessing the need for a confirmatory serology test.
- Negative results do not preclude SARS-CoV-2 infection (false negative) and should not be used as the sole basis for patient management decisions. The sensitivity of the LightDeck COVID-19 Total Antibody Test early after infection is unknown.
- Testing should not be performed when ambient temperature is higher than 30°C.

Test Procedure

1. Double click the icon on the computer to open the LightDeck-T software.
   a. Click RUN TEST
   b. Choose COVID-19 Total Antibody from the drop-down menu.
   c. Enter information into the input fields.
   d. Click ACCEPT to load your inputs.
2. Open the pouch. Remove the cartridge.
   a. Use within 10 minutes.
   b. Avoid touching the clear plastic on the bottom of the cartridge.
   c. Gently remove the blue pull tab from the cartridge inlet port.
3. Using a fresh pipette tip, add 50 µL sample to the sample port of the cartridge.
4. Click READY to open the cartridge door to the analyzer.
5. Insert the cartridge into the analyzer. DO NOT insert if the outside of the cartridge is contaminated with sample. The rest of the procedure is automatic. Results are reported when the test is complete.
6. Remove the cartridge from the analyzer and dispose of it in a biohazardous waste container.

Results

Internal Controls

The cartridge contains two internal controls that are designed to detect within run failure modes and invalidate the test result. If either control fails, the result will be reported as invalid.

Automated Result Calculation

A sample with valid internal controls has the results reported to the user. The instrument measures the fluorescent signal from the RBD detection zones and based on a predetermined relative fluorescence unit (RFU) cutoff reports the ratio of the sample RFU to the cutoff RFU. This ratio is the cutoff index (COI).

$$\text{COI} = \frac{\text{RFU Signal for Sample}}{\text{RFU Signal Cutoff}}$$

Interpretation of Results

Patient results are displayed as Positive (Reactive) or Negative (Non-Reactive)

Numeric	Result	Interpretation
COI < 1.0	NEGATIVE Non-reactive	Specimen is Negative (non-reactive) for anti-SARS-CoV-2 antibodies
COI ≥ 1.0	POSITIVE Reactive	Specimen is Positive (reactive) for anti-SARS-CoV-2 antibodies

The magnitude of the measured result above the cutoff may not be indicative of the total amount of antibody present in the sample.

The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.

A result report is displayed on the laptop, and the report (.pdf file) can be saved on the laptop, saved on a USB stick (not provided), or printed on a Windows 10 compatible printer (not provided).

Conditions of Authorization for the Laboratory

MBio Diagnostics, Inc. (dba LightDeck Diagnostics) is the manufacturer of the LightDeck T Analyzer and LightDeck COVID-19 Total Antibody Test. Pursuant to the instructions detailed in FDA Guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (May 11, 2020), LightDeck Diagnostics has notified FDA that it has completed validation of the test at its Boulder, CO facility. FDA notification was made on September 4, 2020. FDA's independent review of this validation is pending.

Laboratories using the product will include all authorized Fact Sheets with the test result reports. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

Laboratories will use the product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types and authorized materials required to use the product are not permitted.

Performance Data

Sensitivity

Samples from 67 individual patients confirmed to be SARS-CoV-2 positive were tested. Of the 67 PCR + samples, 65 were Positive (Reactive) with the LightDeck COVID-19 Total Antibody Test. The Positive Percent Agreement (PPA) in relation to days post PCR and the 95% confidence intervals were determined. For samples collected after 15 days post PCR, the sensitivity was 98.2% (95% CI: 90-7% - 99.8%).

Days post PCR +	Positive (Reactive)	Negative (Non-reactive)	N	PPA (95% CI)
0-7	8	0	8	100% (67.6-100%)
8-14	1	1	2	50.0% (9.5-90.5%)
≥15	56	1	57	98.2% (90.7-99.8%)

Clinical Specificity

To determine the negative percent agreement (NPA) of the LightDeck COVID-19 Total Antibody Test, 320 serum samples collected prior to December 2019 were tested. The specificity was 99.4% (95% CI: 97.8% - 99.8)

Sample	Positive (Reactive)	Negative (Non-reactive)	N	NPA (95% CI)
Pre-COVID	2	318	320	99.4% (97.8% - 99.8%)

Summary Results

Measure	Estimate	95% CI
Total Ab Sensitivity (PPA)	98.2% (56/57)	90.7% - 99.8%
Total Ab Specificity (NPA)	99.4% (318/320)	97.9% - 99.8%
Positive Predictive Value†	89.6%	76.5% - 100.0%*
Negative Predictive Value†	99.9%	99.7% - 100.0%*

†Calculated based on 5% prevalence

*Variance of predictors calculated using the delta method

Specificity

Interfering Substances

Potentially interfering endogenous and exogenous substances were tested by spiking the substances into positive and negative QC samples as summarized in the table below. All prepared samples were analyzed in 5 replicates. No interference up to concentration listed in the table was observed.

Type	Potentially Interfering Substance	Test Concentration (mg/dL)
Endogenous	Hemoglobin	1000
	Triglycerides	1000
	Cholesterol	40.0
	Bilirubin, conjugated	40.0
	Bilirubin, unconjugated	40.0
Exogenous	Ibuprofen	20.0
	Acetylsalicylic Acid	3.0
	Acetaminophen	15.0
	Naproxen	36.0
	Amoxicillin	5.0
	Ciprofloxacin	1.0

Symbols

For in vitro diagnostic use


Consult instructions for use

Serial number

Batch code/lot number

Catalog number


Use by YYYY-MM-DD


Caution, consult accompanying documents


Electrical hazard


Biological risk/Biohazard


Manufacturer


Date of manufacture


Do NOT recycle. In compliance with European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), this equipment must not be disposed of as unsorted municipal waste. Instead, it must be collected separately in accordance with local recycling regulations. Presence of the symbol indicates that compliance must be adhered to for this device on waste electrical and electronic equipment (WEEE).


DC electrical power rating

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