Avis urgent de sécurité sur le terrain

Les Tests Rapides VivaDiag SARS-CoV-2 IgM/IgG (les Tests Rapides VivaDiag COVID-19 IgM/IgG)
FSCA202003271
Remplacer l'IFU (mode d'emploi)

Date: 27 mars 2020

Attention: remplacer immédiatement l'IFU (mode d'emploi) des Tests Rapides VivaDiag COVID-19 IgM/IgG

Les dispositifs concernés:

Nom de dispositif	Des lots	Quantité	No. Catalogue
Les Tests Rapides VivaDiag COVID-19 IgM/IgG	E2002002, SE2003001 SE2003002, SE2003003	40860 pcs	VID35-08-011

Description du problème:

1. Le nom du produit "Test Rapide VivaDiag COVID-19 IgM/IgG" sur l'IFU, la boîte de kit et l'étiquette n'est pas correct, et devrait rectifié en "Test Rapide VivaDiag SARS-CoV-2 IgM/IgG"
2. Il n'existe pas d'information significative de "l'usage professionnel uniquement" et "pas pour la détection de virus du premier enregistrement" sur l'IFU, la boîte de kit et l'étiquette
3. Le Représentant Européen a été changé de Landlink GmbH (Dorfstrasse,2/4, Emmendingen, Allemagne) à Lotus NL B.V. (Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Pays-Bas) daté du 29 février 2020
4. VivaChek a révisé le mode d'emploi (IFU) avec les modifications ci-dessus (1,2&3)--documents no. 1604003005 (ver 05).

onseil sur les actions à entreprendre par l'utilisateur:

1. Pour les produits des lots ci-dessus, veuillez imprimer le mode d'emploi (IFU) attaché-documents no. 1604003005 (ver 05) et remplacer l'ancien mode d'emploi. Veuilez vous assurer que ce nouveau mode d'emploi (IFU) est disponible pour chaque utilisateur et livré avec chaque boîte des produits.
2. Veuillez noter que le Test Rapide VivaDiag SARS-CoV-2 IgM/IgG EST DESTINE UNIQUEMENT AUX PROFESSIONNELS DE LA SANTE ET AUX LABRATOIRES CLINIQUES. LE TEST A DOMICILE EST DECONSEILLE.

Cordialement,

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SARS-CoV-2 IgM/IgG Rapid Test
Package Insert

REF VID35-08-011 / VID35-08-012 / VID35-08-013 / VID35-08-014 / VID35-08-015	English

PRINCIPLE AND INTENDED USE

VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test (COVID-19 IgM/IgG Rapid Test) is for the rapid, qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human whole blood (fingertip/venous), serum or plasma. The test is for *in vitro* diagnostic use only. For professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.

VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test is based on immunoassay technology. The Test Device contains: 1) Conjugate pad: recombinant SARS-CoV-2 antigen labeled with colloidal gold which linked FITC, FITC antibody and quality control antibody gold marker. 2) NC membrane: coated with two detection lines (IgG line and IgM line) and one quality control line (C line). The IgM detection line coated with mouse anti-human IgM monoclonal antibody detects the SARS-CoV-2 IgM antibody. The IgG detection line coated with mouse anti-human IgG monoclonal antibody detects the SARS-CoV-2 IgG antibody. The quality control line C is coated with quality control antibody.

When specimen is added to the specimen well, it will react with the reagents in the Test Device. If the specimen contains IgM antibody, it will bind to the virus antigen labeled with colloidal gold to form a sandwich complex with the coated anti-human IgM monoclonal antibody at the IgM detection line. The IgM detection line will appear purplish-red indicating the SARS-CoV-2 IgM antibody is positive. If the specimen contains IgG antibody, it will bind to the virus antigen labeled with colloidal gold to form a sandwich complex with the coated anti-human IgG monoclonal antibody at the IgG detection line. The IgG detection line will appear purplish-red indicating the SARS-CoV-2 IgG antibody is positive.

If neither IgG nor IgM detection line appears, the test result will be negative. The Test Device also contains a quality control line C which should appear purplish-red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the IgM or IgG detection lines appear.

COMPOSITION

Each test kit contains the Test Devices, buffer, pipette (optional) and package insert.
Materials required but may not provided: safety lancet (for fingertip blood), alcohol pad or timer.

STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze or refrigerate. Use the test kits at temperatures between 15-30°C.
- Use the test kits between 10-90% humidity.
- Do not use the test kits beyond the expiration date (printed on the foil pouch and box label).

Note: *All expiration dates are printed in Year-Month format. 2021-06 indicates June, 2021.*

WARNINGS, PRECAUTIONS AND LIMITATIONS

- Results from IgM/IgG antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic and / or CT should be considered to rule out infection in these individuals.
- 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. Follow-up testing with a molecular diagnostic and / or CT should be considered to confirm the testing result.
- Not for at-home testing.
- Not for the screening of donated blood.
- Do not use highly hemolytic specimens.
- Further molecular diagnostic and / or CT is recommended to identify the actual physical situation.
- Do not reuse the Test Device. Do not use it beyond the expiration date.
- Only use whole blood (fingertip/venous), serum or plasma as specimens. Follow the package insert to obtain accurate results.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits.

TEST PROCEDURE

Allow the Test Devices and buffer to equilibrate to 15-30°C prior to testing.

1. Place a Test Device on a clean and level surface.
2. Add 10 µL whole blood (fingertip/venous), serum or plasma onto the specimen well of a Test Device.
3. Add 2 drops (about 60-80 µL) of buffer onto the specimen well of a Test Device.
4. Read the test result at 15 minutes. Don't read the result after 20 minutes.

Note: *Handle buffer with caution, avoid any contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*

INTERPRETATION OF TEST RESULTS

1. Positive Results:

Positive SARS-CoV-2 IgM antibody:
Both the quality control line C and the IgM detection line appear, while the IgG detection line does not appear.

Positive SARS-CoV-2 IgG antibody:
Both the quality control line C and the IgG detection line appear, while the IgM detection line does not appear.

Positive SARS-CoV-2 IgM and IgG antibodies:
All 3 lines appear, including the quality control line C and the IgM and IgG detection lines.

2. Negative Result:
Only the quality control line C appears, with no other line appearing on the IgM or IgG detection lines. It indicates the test result is negative for both SARS-CoV-2 IgM and IgG antibodies.

3. Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the IgM or IgG detection line appears or not. Collect a new specimen and perform another test with a new Test Device.

Positive: At least one purplish-red line (IgG, IgM line) and one purplish-red quality control line (C) appear in the detection area.

Negative: Only the quality control line (C) appears in the detection area.

Invalid: No purplish-red quality control line (C) appears in the detection area no matter the IgG/IgM line is colored or not.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE

VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test was evaluated using 200 negative and 150 positive specimens as shown below:

Clinical Performance of negative sample			
Negative Cases (By PCR&CT)	Negative coincidence rate (VivaDiag™ SARS-CoV-2 IgM)	Negative coincidence rate (VivaDiag™ SARS-CoV-2 IgG)	Negative coincidence rate (Total)
200	200 (100%)	200 (100%)	200 (100%)
Clinical Performance of positive sample (Symptoms appeared: 4-10 days)			
Positive Cases (By PCR&CT)	Positive coincidence rate (VivaDiag™ SARS-CoV-2 IgM)	Positive coincidence rate (VivaDiag™ SARS-CoV-2 IgG)	Positive coincidence rate (Total)
80	65 (81.25%)	30 (37.5%)	65 (81.3%)
Clinical Performance of positive sample (Symptoms appeared: 11-24 days)			
Positive Cases (By PCR&CT)	Positive coincidence rate (VivaDiag™ SARS-CoV-2 IgM)	Positive coincidence rate (VivaDiag™ SARS-CoV-2 IgG)	Positive coincidence rate (Total)
70	68 (97.1%)	67 (95.7%)	68 (97.1%)

Relative Specificity: 100%
Relative Sensitivity (Symptoms appeared: 4-10 days, IgM & IgG): 81.3%
Relative Sensitivity (Symptoms appeared: 11-24 days, IgM & IgG): 97.1%
Accuracy (Symptoms appeared: 4-10 days, IgM & IgG): 94.6%
Accuracy (Symptoms appeared: 11-24 days, IgM & IgG): 99.3%
Total accuracy: 95.1%

CROSS-REACTIVITY

The VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test has been tested for SARS-CoV antibody, HPIV antibody, Influenza A&B virus antibody, C. pneumoniae antibody, MP antibody, Adenovirus antibody, RSV antibody, HbsAb, HCV-Ab, TP antibody, HIV antibody, EBV antibody, MLs antibody, CMV antibody, EV71 antibody, Mumps antibody and VZV antibody. The results showed no cross-reactivity.

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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