Procalcitonin Test Kit
Package Insert

REF VID02-01-011	English

SUMMARY

Procalcitonin (PCT) is a protein that increases plasma levels in severe infections caused by bacterial / fungal / parasitic, and in sepsis and multiple organ failure, but not increases in autoimmune, allergic and viral infections; locally limited bacterial, mild and chronic infections will also not cause it to increase. In addition, PCT can be detected in 1-4d of a large number of patients after major surgery. PCT reflects the activity of systemic inflammation and is a parameter for the diagnosis and monitoring of bacterial infections. The measurement of PCT can serve as an acute parameter for the differential diagnosis of bacterial, non-bacterial infections and inflammations; monitoring patients at risk of infection and requiring intensive care.

PRINCIPLE AND INTENDED USE

VivaDiag Procalcitonin test kit is an *in vitro* diagnostic test for the quantitative determination of PCT in human whole blood, serum and plasma. The measurement of PCT can serve as an acute parameter for the differential diagnosis of bacterial, non-bacterial infections and inflammations; monitoring patients at risk of infection and requiring intensive care.

The test kit is consists of test device (including device and desiccant), buffer and code chip. The test kit and analyzer are for *in vitro* diagnostic use only, and can be used in point-of-care testing settings and central laboratories.

The PCT test kit is based on immunochromatography technology. The concentration of PCT in human blood, serum or plasma was quantified by immunofluorescent double antibody sandwich method. The samples were added to the buffer and mixed. The mixed samples were added to the sample hole of the test device, and the tested substances in the sample were combined with the fluorescent labeled antibody coated on the cellulose nitrate membrane to form the reaction complex. Under the action of chromatography, the reaction complex diffused forward along the nitrocellulose membrane and was captured by the PCT monoclonal antibody which was fixed on the detection line of nitrocellulose membrane. The intensity of the fluorescent antibody signal reflects the amount of the captured PCT, and the concentration of the samples in the sample can be detected by the analyzer.

COMPOSITION

Each test kit contains the test device (including device and desiccant), code chip, buffer and package insert.

*** Material required (not supplied with the kit):*

- *Pipette and pipette tips*
- *VivaDiag™ Analyzer*

STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C (36-86°F). Keep away from heat and direct sunlight. Exposure to temperature and / or humidity outside the specified conditions may result in inaccurate results.
- Do not freeze or refrigerate.
- Use the test kits at temperatures between 18-25°C.
- Use the test kits between 10-90% humidity.
- Do not use your test kits beyond the expiry date (printed on the foil pouch and box label).

Note: *The test kit is recommended to store between 2-8°C if it not used in a short time.*
All expiry dates are printed in Year-Month format. 2020-01 indicates January, 2020.

TEST PROCEDURE

1. Take out the test kit and leave it at room temperature for 20 minutes at least, and turn on the Analyzer for 5 minutes
2. Set a test device on a dust-free clean surface.
3. Check and insert code chip into the analyzer. Make sure that the Code Chip matches Test Device.
4. Prick a finger with a lancet to draw whole blood (serum or plasma can be drawn with a blood collection).
5. Apply 50μL (serum or plasma) or 100μL whole blood to the buffer tube.
6. Shake the assembled tube 10 times up and down.
7. Apply only 60μL (serum or plasma) or 75μL (whole blood) the above mixed solution onto the sample well of a Test Device.
8. Insert Test Device onto the holder of the analyzer. Checking the direction of Test device, push the device back all the way.
9. Click the “New Test” button of Standard Test, the analyzer will automatically display the result after 10 minutes.

Note:

- *For in vitro diagnostic use.*
- *Do not mix components from different kit containers.*
- *Avoid contact with eyes and skin. Flush abundantly with water upon disposal if reagents are spilled.*

LIMITATIONS

- The test result cannot be used for confirmed diagnosis. If the result is not matched the clinical evaluation, please do more testing.
- The false results may be caused by the cross-reactions or other non-specific anti-body in the sample.
- The false results may be caused by incorrect operations for sample preparation, sample transfer and so on.
- And some tech factors, wrong operation and wrong samples may be caused wrong test results.
- Please do not reuse the test device.
- This test kit can be only used with fresh whole blood, serum or plasma. If use other samples, it may cause wrong results.
- Please make sure the test temperature is in 18-25°C.
- Please follow the test insert when testing.
- Please contact your local distributor if you have any questions you can not solve.

PERFORMANCE

Accuracy：≤±10%
Test range：0.1-50 ng/mL
Sensitivity：≤0.05 ng/mL
Repeatability：≤10%
Batch-batch difference：≤15%
Reference value: 0.5 ng/mL

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				

VivaChek Laboratories, Inc.
913 N Market Street, Suite 200,
Wilmington, DE 19801, USA
www.vivachek.com

EC REP Landlink GmbH
Dorfstrasse2/4,79312, Emmendingen, Germany
Tel / Fax: 0049 7641 9626855
E-mail: info@landlink.eu

CE

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