



OratectCheck[®] Oral Fluid Controls

Catalog No.: OC-001

This product insert covers the following Alere OratectCheck[®] Oral Fluid Control product:

For *in vitro* diagnostic use only. Read product insert before use. Keep frozen until use.

PRODUCT DESCRIPTION

The Alere OratectCheck[®] Oral Fluid Controls are ready-to-use liquid controls, which are prepared from synthetic saliva. The negative oral fluid control (0.5x cut off) and the positive oral fluid control (2x cut off) are spiked with authentic reference drug standards and are verified by LC/MS/MS.

INTENDED USE

Alere OratectCheck[®] Oral Fluid Controls are used as quality control materials with Alere Oratect[®] Oral Fluid Drug Screen Devices.

This product is intended to be used by health care professionals as an integral part of good laboratory practices.

SUMMARY AND EXPLANATION

The use of quality control materials provides an aid to verify proper test performance and interpretation of positive and negative test results. Testing with Alere OratectCheck[®] Oral Fluid Controls will provide assurance that Alere Oratect[®] Oral Fluid Drug Screen Devices are performing properly.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- The Target Values and Expected Results provided in this package insert are applicable to Alere Toxicology Alere Oratect[®] Oral Fluid Drug Screen Devices only.
- The Alere OratectCheck[®] Oral Fluid Controls and accompanying test procedure are intended for use with Alere Oratect[®] Oral Fluid Drug Screen Devices, which are capable of detecting the presence of specific drugs. See Target Values.
- Read product insert carefully before use.
- Protect from exposure to direct sunlight.
- Contains trace amounts of sodium azide. Caution: To prevent formation of explosive metal azides, dispose of waste by flushing with copious amount of water according to local government regulations.
- Do not return any unused control material back into the original bottle sample.

REAGENTS AND MATERIALS

Description	Contents	Ingredients
Alere OratectCheck [®] Oral Fluid Negative Control	3 mL	Synthetic saliva with spiked drugs (see target values)
Alere OratectCheck [®] Oral Fluid Positive Control	3 mL	

TEST PROCEDURES

1. Allow the Alere OratectCheck[®] Oral Fluid Controls to thaw and warm to room temperature followed by gentle swirling or inversion before use. **DO NOT WARM BY HEATING.**
2. Use a transfer pipette to drop oral fluid specimen onto collection pad of device slowly. Be sure the pad has absorbed the first droplet before placing the next drop on the pad.
3. As soon as the blue lines move in both windows, there is sufficient amount of oral fluid to complete the test, stop adding the oral fluid drops to avoid flooding.
Note: The normal volume range of droplets needed for the blue lines to move is between 15 to 20 droplets. If more than 25 droplets have been added and the blue lines do not move, discard the device, review the procedure and repeat the test with a new device.

4. Cap the device, lay it on a flat surface and read results in approximately 5 minutes. Do not read results after 15 minutes.
5. Verify the control test result with the target values and expected results below.
6. If test result differs from expected result, check and verify that the storage conditions, expiration date of both the control and the test device are within the specified limits. Repeat the test using a new bottle of control.

TARGET VALUES AND EXPECTED RESULTS

The Positive control should have **NO LINE** in the test area

Positive Control

Constituents	Target Values (ng/mL)*	Expected Results
ME	100	Positive
TH	80	Positive
CO	40	Positive
AM	100	Positive
OP	80	Positive
PC	20	Positive

The Negative control should show a **LINE** in the test area

Negative Control

Constituents	Target Values (ng/mL)*	Expected Results
ME	25	Negative
TH	20	Negative
CO	10	Negative
AM	25	Negative
OP	20	Negative
PC	5	Negative

* Target values have been verified by LC/MS/MS methodology performed by a SAMHSA certified laboratory.

LIMITATION OF PROCEDURE

1. Consult manufacturer's instructions when using this product; changes in reagents, sample requirements, or methodology may affect test results.
2. Although target values are provided with the Alere OratectCheck[®] Oral Fluid Controls, each laboratory should run these controls as "unknowns" in order to establish its own specification.
3. This product is not meant to be used as a standard or calibrator.

STORAGE AND STABILITY

Upon receiving the Alere OratectCheck[®] Oral Fluid Controls stored as follows:

Unopened: The unopened controls are stable until the expiration date when stored frozen at -10 to -20°C (14 to -4°F) and protected from light.

Opened: Once opened the controls are stable for 7 days or until the expiration date, whichever comes first, when stored at 2 to 8°C (35.6 to 46.4°F) and protected from light.

REFERENCES

1. Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
2. Wong, R. On-site Oral Fluid Drug Testing by Oratect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-158, 2005.

Manufactured for: **Alere Toxicology Services – Products Division**
Portsmouth, VA 23704 USA
Phone: 1-800.340.4029
Fax: 1-888.340.4029
Web: www.aleretoxicology.com

© 2013 Alere. All rights reserved.
The Alere Logo, Alere, Oratect and OratectCheck are trademarks of the Alere group of companies.

Part No.: PI-X11-OC-001 Rev: A, 07/2013