COMBI DIPSTICK

For *in Vitro* **diagnostic use only**

Immunochromatographic test strip for the detection of Rotavirus and Adenovirus antigens in human faeces

I. INTRODUCTION AND INTENDED USE

Viral gastroenteritis is an infection caused by a variety of viruses that results in vomiting or diarrhea. Many different viruses can cause gastroenteritis, including rotaviruses, adenoviruses, astroviruses and noroviruses.
The main symptoms of viral gastroenteritis are watery diarrhea and vomiting. The affected person may also have headache, fever, and abdominal cramps ("stomach ache"). In general, the symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last for 5-8 days. Rotavirus is the more frequent cause of acute diarrhea in children under two years of age. Adenoviruses and Astroviruses cause diarrhea mostly in young children, but older children and adults can also be affected.
COMBI DIPSTICK is a screening immunochromatographic assay to detect Rotavirus and Adenovirus in stool samples.

II. PRINCIPLE

Combi Dipstick is a non-invasive lateral flow assay, rapid, precise and easy to perform. The membrane is pre-coated with monoclonal antibodies against Adenovirus and Rotavirus antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Adenovirus antibodies and/or anti-Rotavirus antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate coloured lines (red for Rotavirus and blue for Adenovirus). A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

III. REAGENTS AND MATERIALS

Each kit contain:
1. Combi Dipstick (25 test): tube containing 25 reactive strips and dissecant.
2. Dilution buffer (1 x 20 mL): saline solution buffered to pH 7,5, containing NaN_3 (< 0.1%), a detergent and charged proteins..
3. Instruction for use (1)

Required materials (not supplied)

Specimen collection container, Disposable gloves, Plastic pipettes, testing tubes or vials, Timer or clock.

AUXILIARY REAGENTS (Not supplied with this kit)

Positive and Negative control (Mascia Brunelli REF.UD80015 and UD80020)

IV. PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- The kit is for in vitro diagnosis only.
- Wear gloves when handling the samples.
- Never use reagents from another lot.
- The tube containing the sensitized strips must be recapped as soon as the necessary number of strips for the operation has been removed, since the strips are sensitive to humidity. Make sure that the desiccant is present.
- Discard the dilution buffer if it is contaminated with bacteria or mould.
- The reagents' quality cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
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V. STORAGE

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

VI. SAMPLES AND PREPARATION

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing. Specimens may be frozen and thawed twice.

VII. PROCEDURE

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the tube with strips until ready to perform the assay. Write the specimen number on the test tube (one test tube per sample). Place the marked test tubes in a rack.

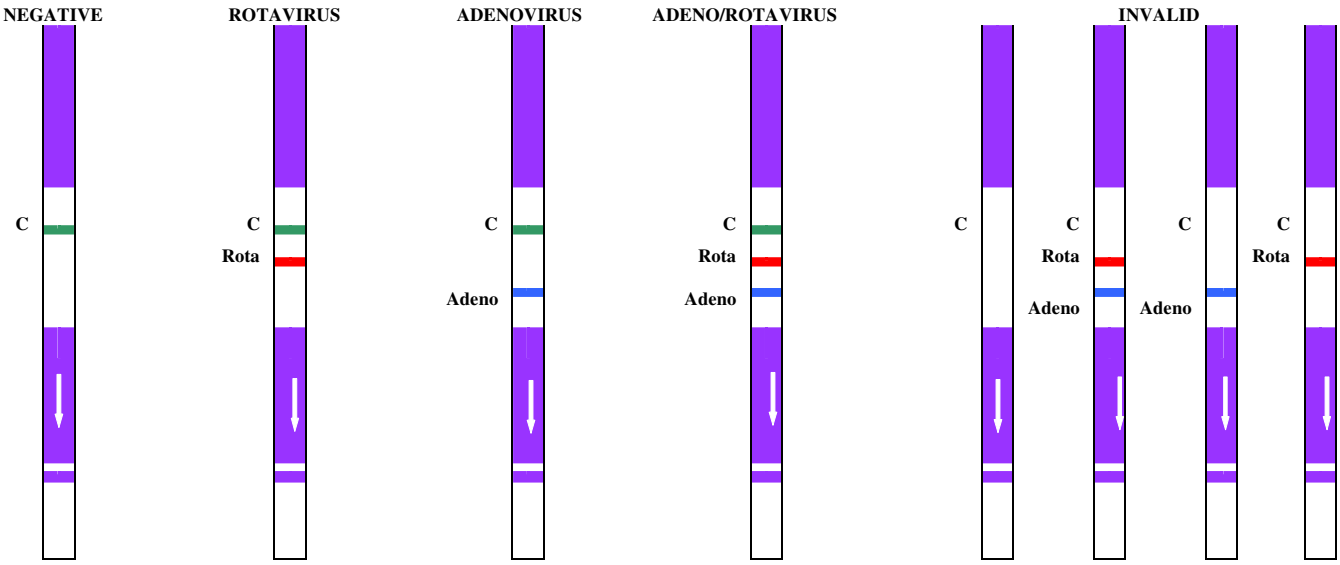
1. Dispense exactly 0,7 mL of the buffer (or 15 drops) into a testing tube.
2. Introduce the swab or stick two times into the faecal specimen to pick up a little sample (100 mg) and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 100 µL into the testing tube or vial with buffer.
3. Stir thoroughly to homogenize the solution, wait 1-2 minutes.
4. Discard the stick and immerse the sensitized strip in the direction indicated by the arrows.
5. Let react for 10 minutes. Results must be read on wet strip after 10 minutes incubation.

To avoid diluting the latex conjugate in the solution, take care not to immerse the strip above the line placed under the arrows.

VIII. INTERPRETING THE RESULTS

Negative test: In the case only one line appears in the control line region (green control line).
Rotavirus positive test: In the case two lines appears across the central window, in the Result Line Region (red test line) and in the control line region (green control line). The sample is positive to Rotavirus
Adenovirus positive test: In the case two lines appears across the central window, in the Result Line Region (blue test line) and in the control line region (green control line). The sample is positive to Adenovirus.
Rotavirus/Adenovirus positive test: In the case three lines appears across the central window, in the Result Line Region (red and blue test line) and in the control line region (green control line). The sample is positive to both Adeno/Rotavirus
Invalid test: The absence of the migration control line, which is the upper line, makes the result invalid. In this case, the sample must be retested.

Care attention that a weak signal on the test line must be regarded as a positive result.



IX. PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The kit was validated comparing the results obtained with Combi Dipstick versus those ones obtained with an ELISA test .
Sensitivity and specificity of kit have been determined on 102 stool samples. The results are:

Adenovirus Sensitivity > 90% Adenovirus Specificity > 99%
Rotavirus Sensitivity > 99% Rotavirus Specificity > 98%

Interference

No cross-reactions have been found with bacteria and substances normally present in the gastro-intestinal tract and those ones generally infecting the same area such as Astrovirus, Escherichia coli, Campylobacter, Giardia lamblia, human hemoglobin.

X. LIMITS OF THE TEST

- Combi Dipstick is screening test for determination of presence of Adenovirus and/or Rotavirus in human faeces. A definitive clinical diagnosis should be made by the physician after all clinical and laboratory findings have been evaluated.
- A positive result does not rule the possibility that other pathogens may be present.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Adenovirus/Rotavirus infection.
- The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

XI. BIBLIOGRAPHIC REFERENCES

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5. Evaluatie van de Immunochromatografische Isolatie van Rota- an Adenovirus. C. Tessa, M. Van Ranst Thesis, UZ Gasthuisberg Leuven, 2000
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IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests) **Ref. VC1004**

Combi Disptick	25 items
Diluent buffer	1 x 20 mL
Instruction for use	1 item

EDMA (EDMS) CODE 15709090 CE IVD