TruQuick™ Rota/Adeno Combo 25T

A rapid, one step test for the qualitative detection of rotavirus and adenovirus in feces.

REF **TQ5025** IVD **Rx Only**

INTENDED USE
TruQuick Rota/Adeno Combo is a rapid immunoassay for the qualitative detection of rotavirus and adenovirus in feces specimens to aid in the diagnosis of rotavirus or adenovirus infection. The results are used in conjunction with other tests and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Acute diarrhea disease in young children is a major cause of morbidity worldwide and is a leading cause of mortality in developing countries.[1] Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children.[2] Its discovery in 1973 and its association with infantile gastroenteritis represented a very important advancement in the study of gastroenteritis not caused by acute bacterial infection. Rotavirus is transmitted by oral-fecal route with an incubation period of 1-3 days. Although specimens collected within the second and fifth day of the illness are ideal for antigen detection, the rotavirus may still be found while diarrhea continues. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly and immunocompromised patients.[3] In temperate climates, rotavirus infections occur mainly in the winter months. Endemics as well as epidemics affecting some thousand people have been reported.[4] With hospitalized children suffering from acute enteric disease, up to 50% of the analyzed specimen are positive for rotavirus.[5] The viruses replicate in the cell nucleus and tend to be host species specific, producing a characteristic cytopathic effect (CPE). Because rotavirus is extremely difficult to culture, it is unusual to use isolation of the virus in diagnosing an infection. Instead, a variety of techniques have been developed to detect rotavirus in feces.

Research has shown that enteric adenoviruses, primarily Ad40 and Ad41, are a leading cause of diarrhea in many children, second only to the rotaviruses.[6-9] These viral pathogens have been isolated throughout the world, and can cause diarrhea in children year round. Infections are most frequently seen in children less than two years of age, but have been found in patients of all ages. Further studies indicate that adenoviruses are associated with 4-15% of all hospitalized cases of viral gastroenteritis.[5-9] Rapid and accurate diagnosis of gastroenteritis due to adenovirus is helpful in establishing the etiology of gastroenteritis and related patient management. Other diagnostic techniques such as electron microscopy (EM) and nucleic acid hybridization are expensive and labor-intensive. With the self-limiting nature of adenovirus infection, such expensive and labor-intensive tests may not be necessary.

TruQuick Rota/Adeno Combo is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in feces specimen, providing results in 10 minutes. The test utilizes antibodies specific for rotavirus and adenovirus to detect and differentiate rotavirus and adenovirus.

BIOLOGICAL PRINCIPLES
In this test, the membrane is precoated with anti-rotavirus antibody on the T1 test line region and anti-adenovirus antibody on the T2 test line region of the Test Cassette. During testing, the specimen reacts with the particle coated with anti-rotavirus antibody and anti-adenovirus antibody. The mixture migrates upward on the membrane by capillary action to react with anti-rotavirus antibody or anti-adenovirus antibody on the membrane to generate colored lines. The presence of these colored lines in test line regions indicate a positive result, while their absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The test contains anti-rotavirus antibody and anti-adenovirus antibody-coated particles and anti-rotavirus antibody and anti-adenovirus antibody coated on the membrane.
- Specimen Collection Tubes with Extraction Buffer. A buffered extraction solution containing ProClin 300 as a preservative. The Tubes are supplied ready for use.
- Package insert
- Dropper

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Pipette capable of delivering 80 µL
- Timer

PRECAUTIONS
- All reagents are for in vitro diagnostic use only. Do not use after expiration date.
- The Test Cassette should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

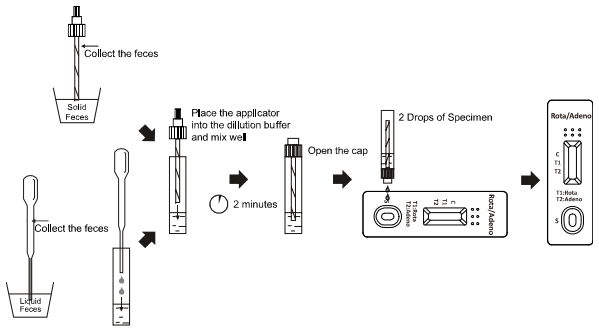
SHELF LIFE AND STORAGE
Store as packaged in the sealed pouches either at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch containing desiccant until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus and adenovirus in the feces of patients with gastroenteritis occurs three to five days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
2. The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
3. Bring the necessary reagents to room temperature before use.

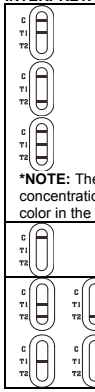
TEST PROCEDURE
Allow the Test Cassette, specimen, and Extraction Buffer to reach room temperature (15-30 C) prior to testing.
1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain enough virus particles. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 C if not tested within 6 hours. For long-term storage, specimens should be kept below -20 C.
2. To process fecal specimens:
   - **For <u>Solid Specimens</u>**:
     Unscrew the cap of the Specimen Collection Tube, then randomly **stab the specimen collection applicator into the fecal specimen in at least 3 different sites** to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - **For <u>Liquid Specimens</u>**:
     Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 50 µL) into the Specimen Collection Tube containing the Extraction Buffer.

   Tighten the cap onto the Specimen Collection Tube, then **shake the Specimen Collection Tube vigorously** to mix the specimen and the Extraction Buffer. Leave the collection tube sit for 2 minutes.
3. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the Specimen Collection Tube upright and open the cap on the tip. Invert the Specimen Collection Tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read the results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimen contained in the Specimen Collection Tube. Collect 80 µL of supernate, dispense into the specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.



INTERPRETATION OF RESULTS



POSITIVE:
Rotavirus Positive: * A colored line appears in the control line region (C) and another colored line appears in the T1 line region.

Adenovirus Positive: * A colored line appears in the control line region (C) and another colored line appears in the T2 line region.

Rotavirus and Adenovirus Positive: * A colored line appears in the control line region (C) and colored lines appear in T1 line region and T2 line region, respectively.

***NOTE:** The intensity of the color in the test line region (T1/T2) will vary depending on the concentration of rotavirus or adenovirus antigens present in the specimen. Any shade of color in the test line region (T1/T2) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T1/T2).

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new Test Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridians Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick Rota/Adeno Combo has been compared with a latex agglutination method, demonstrating an overall correlation of ≥ 97.0%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Rota/Adeno Combo is for in vitro diagnostic use only. The test should be used for the detection of human rotavirus and adenovirus in feces specimens only. Neither the quantitative value nor the rate of increase in human rotavirus and adenovirus concentration can be determined by this qualitative test.
2. TruQuick Rota/Adeno Combo will only indicate the presence of rotavirus and adenovirus in the specimen and should not be used as the sole criteria for the conforming rotavirus and adenovirus to be etiological agent for diarrhea.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 rotavirus or adenovirus infection with low concentration of virus particles.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Rota/Adeno Combo was evaluated in comparison with a latex agglutination method with clinical specimens collected from children and young adults. The results show that TruQuick Rota/Adeno Combo has high sensitivity and specificity for rotavirus and adenovirus.

Method		Latex Agglutination Rotavirus		Total Results
TruQuick Rota/Adeno Combo	Results	Positive	Negative	
	Positive	251	7	258
	Negative	7	236	243
Total Results		258	243	501

Sensitivity: 97.3% (95% CI:*94.5%-98.9%)
Specificity: 97.1% (95% CI:*94.2%-98.8%)
Correlation: 97.2% (95% CI:*95.4%-98.5%) *Confidence Intervals

Method		Latex Agglutination Adenovirus		Total Results
TruQuick Rota/Adeno Combo	Results	Positive	Negative	
	Positive	118	6	124
	Negative	6	251	257
Total Results		124	257	381

Sensitivity: 95.2% (95% CI:*89.8%-98.2%)
Specificity: 97.7% (95% CI:*95.0%-99.1%)
Correlation: 96.8% (95% CI:*94.6%-98.4%)
*Confidence Intervals

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision has been determined by using 10 replicates of seven specimens: a negative, a rotavirus low positive, an adenovirus low positive, a rotavirus medium positive, an adenovirus medium positive, a rotavirus high positive and an adenovirus high positive.. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision

Between-run precision has been determined by 10 independent assays on the same seven specimens: a negative, a rotavirus low positive, an adenovirus low positive, a rotavirus medium positive, an adenovirus medium positive, a rotavirus high positive and an adenovirus high positive. Three lots of TruQuick Rotavirus were used. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

Crossreactivity was assessed with the following organisms at 1.0 x 10^9 organisms/mL. None of the organisms reacted with TruQuick Rota/Adeno Combo.

Staphylococcus aureus	*Proteus mirabilis*	*Neisseria gonorrhea*
Pseudomonas aeruginosa	*Acinetobacter spp*	Group B *Streptococcus*
Enterococcus faecalis	*Salmonella choleraesius*	*Proteus vulgaris*
Group C *Streptococcus*	*Gardnerella vaginalis*	*Enterococcus faecium*
Klebsiella pneumoniae	*Acinetobacter calcoaceticus*	*Hemophilus influenzae*
Branhamella catarrhalis	*E. coli*	*Neisseria meningitidis*
Candida albicans	*Chlamydia trachomatis*	Group A *Streptococcus*
		Helicobacter pylori

ANALYTICAL SENSITIVITY

The detection limits for this assay are 1 x 10^7 org/mL for Rotavirus and 2.5 x 10^7 org/mL for Adenovirus.

TESTS FOR INTERFERING SUBSTANCES

TruQuick Rota/Adeno Combo was tested with the following potential interferents. None reacted with the assay at the concentrations tested.

Ascorbic acid 20 mg/dL	Urea 2 g/dL
Oxalic Acid 60 mg/dL	Glucose 2 g/dL
Bilrubin 100 mg/dL	Caffeine 40 mg/dL
Uric acid 60 mg/dL	Albumin 2 g/dL
Acetylsalicylic acid 20 mg/dL	

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SNTQ5025 **REV. 05/17**

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SYMBOL USAGE

You may see one or more of these symbols on the labeling/packaging of this product:

Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer	⚠	Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	R_x Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.