MICROGEN BIOPRODUCTS

M81 Adenoscreen ®

50

CE

IVD

1. INTENDED USE

Adenoscreen® is a rapid and simple latex agglutination test for the detection of Adenovirus antigen in faecal specimens. The test is intended for professional use only.

2. PRINCIPLE OF THE TEST

Latex particles in the Adenoscreen® Test Reagent are coated with rabbit antibodies raised against an Adenovirus hexon preparation.
When a faecal extract is mixed with the Test Reagent any Adenovirus antigens present will react with the sensitising antibodies, resulting in visible agglutination of the latex particles.
A Control Reagent, latex particles coated with normal rabbit globulin, is included to identify non-specific reactions which may occur with some faecal specimens.

3. CONT

REAG TEST M81a 2.5mL
Test reagent - Contains (rabbit) Adenovirus antibody-sensitised latex particles in buffer, with stabiliser, and 0.099% sodium azide as preservative.

REAG CONTROL M81b 2.5mL
Control Reagent - Contains (rabbit) normal globulin-sensitised latex particles in buffer, with stabiliser, and 0.099% sodium azide as preservative.

CONTROL + M81c 1.0mL
Positive Control - Contains inactivated bovine Adenovirus antigens in buffered cell culture medium, with antibiotics, and 0.099% sodium azide as preservative.

SAMP DIL M80d 50mL
Sample Diluent - Contains working strength buffer, pH 7.2, and 0.099% sodium azide as preservative

Disposable Reaction Cards
Disposable Mixing Sticks

4. ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory centrifuge.
Stoppered or screw-capped tubes.

5. PRECAUTIONS

5.1 Adenoscreen® is for *in vitro* use only.
5.2 Do not use reagents after the kit expiration date.
5.3 Do not interchange reagents from different kit lots.
5.4 The test should only be performed in accordance with the instructions supplied with the kit.
5.5 Do not pipette specimens or reagents by mouth.

5.6 All clinical specimens should be considered infectious, handled and disposed of according to accepted practices. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30minutes. Liquid waste containing acid must be neutralised before treatment.

5.7 The Positive Control is prepared from *inactivated* adenovirus. However, it should be considered as potentially infectious and handled in the same way as a clinical specimen.

5.8 The reagents in this kit contain sodium azide as preservative which may react with lead and copper plumbing to form highly explosive azides. Upon disposal, flush with a large volume of water to prevent azide building up.

6. STORAGE

Store all reagents at 2-8^{0}C. **Do not freeze**. Under these conditions the reagents will be usable until the date printed on the outer carton label.

7. INDICATIONS OF DETERIORATION

Deterioration should be suspected if:

- Clumping of the Test Reagent (M81a) or Control Reagent (M81b) is evident and cannot be removed by gentle mixing.
- The Positive Control (M81c) or Sample Diluent (M80d) becomes cloudy or forms sediment.
- The Positive Control (M81c) fails to cause agglutination of the Test Reagent (M81a) within the recommended reaction time.

Reagents showing signs of deterioration should not be used.

8. SPECIMEN STORAGE AND PREPARATION

Faecal samples should be tested as soon after collection as possible but, if necessary, they may be stored overnight at 2-8^{0}C or for longer periods at -20^{0}C or below.
Prepare an approximate 10% suspension of faecal specimen by transferring 0.1mL (0.1 g) of sample into 1.0 mL of Sample Diluent in a stoppered or screw-capped tube. Mix the contents well.
Allow to stand at room temperature for 1-2 minutes before proceeding with the test.

9. USE OF THE POSITIVE CONTROL

The Positive Control should be tested regularly to ensure that the reagents are functioning correctly. The control is ready for use and should be tested in place of the specimen extract in the Test Procedure.
The Positive Control should give agglutination of the Test Latex Reagent with no agglutination of the Control Latex Reagent. Failure to give this agglutination pattern is evidence of reagent deterioration.

10 TEST PROCEDURE - STANDARD METHOD USING CENTRIFUGE

10.1 Process the specimen as described in Section 7.
10.2 Allow the reagents to reach room temperature.
10.3 Centrifuge the specimen extract at approximately 1000g for 10 minutes.
10.4 Pipette 50µL of clear supernatant onto each of two wells on the Test Slide.
10.5 Add 1 drop of well mixed Test Reagent (M81a) to one well and 1 drop of well mixed Control Reagent (M81b) to the other.
10.6 Mix the contents of each well using a separate mixing stick for each sample, covering the entire area of the well.
10.7 Gently rock the slide and observe for agglutination up to two minutes.

11 TEST PROCEDURE - FILTER METHOD USING MICROGEN BIOPRODUCTS FILTER PACK M802

11.1 Process the specimen as described in Section 8.
11.2 Allow the reagents to reach room temperature.
11.3 Remove the stopper and fit integral filter/dropper unit
11.4 Holding the whole assembly vertically dispense 1 drop of clear filtrate onto each of two wells on the Test Slide.
11.5 Add 1 drop of well mixed Test Reagent (M81a) to one well and 1 drop of well mixed Control Reagent (M81b) to the other.
11.6 Mix the contents of each well using a separate mixing stick for each sample, covering the entire area of the well.
11.7 Gently rock the slide and observe for agglutination up to two minutes.

12. INTERPRETATION OF RESULTS

a) A **positive** result is indicated by agglutination of the Test Reagent (M81a) with no agglutination of the Control Reagent (M81b).
b) The result is **negative** if no agglutination of either the Test Reagent (M81a) or the Control Reagent (M81b) is observed within the 2 minute test period.
Note: Agglutination of the Control Reagent (M81b) is evidence of a non-specific reaction and means that the specimen is unsuitable for testing by this method.

13. LIMITATIONS OF THE PROCEDURE

Adenoscreen® results should be evaluated in the light of all other available clinical and laboratory information.
A positive Adenoscreen® test does not preclude the possibility of other microbial co-infections.
Adenoscreen® is intended as an acute-phase test. Faecal samples collected after the acute phase may contain antigen concentrations below the threshold of reagent sensitivity.
Adenoscreen® has been designed for the detection of enteric strains of adenovirus. It may not detect for example all respiratory strains.

14. PERFORMANCE CHARACTERISTICS

Adenoscreen® has been evaluated against faecal samples characterised by electron microscopy (EM) at leading microbiology laboratories in the United Kingdom.
236 stool specimens were tested for adenovirus by Adenoscreen® and electron microscopy (EM).
The results can be summarised as follows:

		Adenoscreen®	
		+	**-**
EM Results	+	51	2**
	-	1*	182

From the 236 samples tested the sensitivity and specificity were as follows:

Sensitivity	96%
Specificity	99%

* This sample was retested by other commercial kits, which also tested positive.
** It was possible to retest 2 out of 3 of these samples with other commercial kits, which also tested negative.

Only 2 samples gave background (±) results against the Control Latex Reagent, although this occurred with samples stored for 4 months at 4^0C.

One Adenovirus positive sample gave a non specific result with the control latex of Adenoscreen® and also another commercial kit.

Cross Reactivity

The following microorganisms showed no cross reactivity when tested with Adenoscreen®:

Viruses (Faecal samples)
Rotavirus
Astrovirus
SRSV

Other Organisms (from plate colonies)

Escherichia coli	Streptococcus Group A
Staphylococcus aureus	Streptococcus Group C
Salmonella spp	Streptococcus Group F
Shigella sonnei	Streptococcus Group G
Neiseria meningitidis	Klebsiella pneumoniae
Haemophilus influenzae	Pseudomonas aeroginosa
Clostridium perfringens	Bacillus spp
Streptococcus pneumoniae	Aeromonas spp
Campylobacter spp	Candida albicans

Acinitobacter (coarse granular precipitation seen in control and test latex)

Intra/inter Batch reproducibility

Intra batch reproducibility has been determined by testing ten times a panel of 5 clinical samples, serial dilutions of a sensitivity standard and kit positive control, using three different operators. The results were 100% concordant in respect of the positive / negative interpretations obtained. The maximum difference in sensitivity readings of the test latex with serially diluted positive samples was one serial dilution.

Interbatch reproducibility has been established for Adenoscreen over a number of years by monitoring each batch against reference panels of samples and serial dilutions of a sensitivity standard.

Microgen Bioproducts Ltd
Unit 1, Watchmoor Point
Camberley
Surrey, GU15 3AD, UK

WF 6190/09/2017(2)