**INTRODUCTION:**

C. difficile, Rotavirus and Adenovirus are the causitive agents of gastroenteritis in children and adults. Appropriate specimen collection and transport devices are essential to improve diagnosis. The FecalSwab kit (a flocked swab and a tube with 2 ml semi-liquid modified Cary Blair medium), original produced in 2008, has now been improved and is in compliance with the new CLSI M44-A guidelines for support of enteric pathogens viability. Stool samples transported in FecalSwab can be processed on the Walk Away Specimens Processor (WASP®) for bacteria culture, and can also be tested for antigens, toxins and nucleic acids detection of bacteria and viruses causing gastrointestinal infections.

**OBJECTIVE:**

The objective of this study was to validate the performance of new FecalSwab device for stools, for the detection of Rotavirus, Adenovirus and C. difficile with rapid antigens, toxins and nucleic acid with real-time PCR assays.

**METHODS:**

Clinical stools (n=130) samples submitted to Synlab laboratory (Brescia, Italy) for the detection of Rotavirus, Adenovirus and C. difficile were used for this validation. The flocked swab from the FecalSwab was used to transfer the stool in the tube medium; duplicate specimens were prepared from each sample.

For rapid kit antigen and toxins detection, FecalSwab samples were vortexed and 200 ul or the flocked swab were used as per kit package insert's procedure. These kits were tested:
- R-Biopharm RidaQuick Rota/Adeno combitrap kit
- R-Biopharm RidaQuick C. difficile toxin A/B kit
- Meridian Rapid Strip Rota-Adeno kit
- Meridian Rapid Strip Rotavirus kit
- Meridian ImmunoCard Stat Rotavirus kit
- Coris Rota Adeno combitrap rapid kit

For nucleic acids detection, FecalSwab samples were vortexed and 200 ul of medium from each sample were used for nucleic acid extraction as manufacturer's procedure.

Nucleic acids were extracted with:
- Qiagen QIamp DNA Stool Mini Kit for DNA extraction from C. difficile
- Norgen Biotek Nucleic Acid for RNA extraction from Rotavirus
- Applied Biosystem PrepSEQ Express on AutoMateExpress DNA extractor for DNA extraction from Adenovirus.

Five ul of extracted nucleic acids were tested by real time PCR as manufacturer's procedure on the ABI 7500 Real Time PCR System with the R-Biopharm RIDA®GENE Viral Stool panel II and RIDA®GENE Clostridium difficile & Toxin A/B.

**RESULTS:**

1. Good correlation found between the original results tested by Synlab laboratory and by Copan. In the 130 stool samples tested were found 34 Adenovirus, 43 Rotavirus, 30 C. difficile toxin A/B positive and 23 negative.

2. Stool samples stored in Copan FecalSwab were detected positive or negative with the following rapid assays: R-Biopharm RidaQuick Rota/Adeno combitrap kit, Meridian Rapid Strip Rota-Adeno kit, Meridian ImmunoCard Stat Rotavirus, Meridian ImmunoCard Stat Adenovirus kit, Coris Rota Adeno combitrap rapid kit and the RidaQuick C. difficile toxin A/B kit.

3. The same stool sample stored in FecalSwab, tested by real Time PCR with R-Biopharm RIDA®GENE Viral Stool panel II and RIDA®GENE Clostridium difficile & Toxin A/B confirmed the results: 34 Adenovirus positive, 43 Rotavirus positive, 30 C. difficile positive and 23 negative.

4. It is important to observe that:
   - No inhibition of the amplification occurred: the pre-lysis step was essentail for stool samples stored in FecalSwab for successful nucleic acids extractions
   - No interference was detected with the performance of stool samples in FecalSwab with all the rapid antigen and toxins assays.

**CONCLUSIONS:**

Stools samples stored and transported in Copan FecalSwab device are compatible with the R-Biopharm, Meridian, and Coris rapid antigen and toxin tests.

Equivalent results were obtained with the R-Biopharm RIDA®GENE Viral Stool panel II and Clostridium difficile & Toxin A/B Real-Time PCR assays. The FecalSwab can be used for the collection of rectal swabs samples for the detection of Adenovirus Rotavirus antigens, C.difficile toxins and nucleic acids.

Stool samples can be easily transferred in the FecalSwab medium with the flocked swabs, are transported in a leak proof tube, occupy less storage space in the refrigerator and are compatible with WASP automation.