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Summary of Safety and Effectiveness

Excel OneStep Group A Strep Antigen Module Test

Excel OneStep Group A Strep Antigen Module Test is Excel Scientific, Inc.'s name for the professional use of solid phase migratory chromatography immunoassay *in vitro* diagnostic test kit for the qualitative detection of group A strep antigen from throat swabs. During correlation studies, prior to using the Excel OneStep Group A Strep Antigen assay, each throat swab was used to inoculate a sheep blood (trypticase) soy agar plate for culture. Group A Streptococci were confirmed by a latex agglutination assay (a commercially available strep grouping kit from Diagnostic Product Corporation, Los Angeles, CA). The exact difference between the two methodologies are as follows:

1. The Excel OneStep Group A Strep Antigen Module Test utilizes the chemical extraction of a carbohydrate antigen from group A streptococcus from the throat swabs followed by the utilization of migratory color immunoassay technology for the qualitative detection of group A streptococcus. The test module has two polyclonal antibodies , one immobilized on the porous membrane, while the other antibody on an absorbent near the sample application is conjugated with colloidal gold particles as signaling molecules. A swab specimen taken from a patient's throat is treated with a fresh mixture of Reagent A and Reagent B to extract out the group A streptococcus antigen. The extract is then transferred to the reaction module with the aid of a transfer pipette and allowed to migrate throughout the absorbent and porous membrane in the reaction module by capillary action until it reaches the opposite end of the read window (in approximately 6~7 minutes). The antibody-antigen-antibody/colloidal gold double antibody sandwich assay is formed if strep A antigen is present in the throat swab. If two colored lines develop in the read window, one in the test zone and the other in the control zone, the presence of strep A antigen is indicative. The absence of this antigen will result in only a single color line located in the control zone in the read window. The appearance of a single colored line for negative specimens also gives an added measure of quality control by demonstrating antibody recognition, assuring that the procedure was performed correctly and that the reagents are chemically active. A drying agent is enclosed with the reaction module in a sealed foil pouch to ensure the stability of the reactive reagents.

2. In the culturing procedure, isolation of streptococcal group A organisms includes the use of culture plates followed by a confirmation assay (such as DPC's latex agglutination strep grouping kit) for strep A. A sheep blood (trypticase) soy agar plate (containing 5% or 10% sheep blood) is used for the cultivation and isolation of microorganisms from the throat swabs and for visualizing hemolytic reactions.