K955108

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

APR 15 1996

Product:
CARDS® Q.S.® Strep A; or
Concise® Performance Plus™ Strep A

Distributor:
Pacific Biotech, Incorporated
a subsidiary of QUIDEL Corporation
10165 McKellar Court
San Diego, CA 92121

Device Classification:
The device, CARDS Q.S. Strep A (also sold under the brand name Concise Performance Plus Strep A), is similar to other FDA-cleared devices used for the qualitative detection of group A streptococcal antigen from throat swab specimens, thereby aiding in the diagnosis of diseases caused by group A *Streptococcus*. The FDA has proposed that serological tests systems for the identification of group A *Streptococcus* from clinical specimens be classified as Class I.

Intended Use:
The CARDS Q.S. Strep A/Concise Performance Plus Strep A is a sensitive immunoassay for the qualitative detection of group A streptococcal antigen from throat swab specimens. This test is to be used to aid in the diagnosis of diseases caused by group A *Streptococcus*. The test is for use by health care professionals.

Physiologic Basis for the Test:
Group A *Streptococci* are organisms that typically cause illness such as tonsillitis, pharyngitis and scarlet fever. If untreated, these infections can lead to complications such as rheumatic fever and glomerulonephritis.

Principle of the Test:
To perform the test, a throat swab specimen is collected. Antigen is extracted from the swab specimen with Reagents A and B. The extracted sample is added to the Reaction Unit.

If the sample contains strep A antigen, a pink vertical line forms in the Read Result Window. This pink vertical line, together with the pre-printed blue horizontal line, form a plus sign (+) to indicate a positive result. If strep A antigen is not present in the sample, the Read Result Window shows only the pre-printed blue horizontal line, forming a minus sign (-) to indicate a negative result.

As the sample continues to move through the test, the procedural Control Window containing strep A antigen becomes pink. Pink color in the Control Window confirms that the test is functionally active and has been performed correctly. The appearance of blue color in the Test Complete Window indicates the completion of the test. This occurs within approximately 5 minutes of adding the extracted sample to the Reaction Unit.

Safety and Effectiveness:
Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to other commercially available products for qualitative detection of group A streptococcal antigen. These studies included the following:

1. The test was shown to be similar to other commercially distributed tests in terms of features and intended use.

2. The test was shown to have excellent intra- and inter-assay precision.

3. Lot-to-lot consistency analyses showed the test to be reproducibly manufacturable.

4. Common bacterial microorganisms and potentially interferring substances were shown not to interfere with the test's performance.

5. A multi-center evaluation of the CARDS Q.S. Strep A/Concise Performance Plus Strep A test was conducted to determine the clinical performance of the test relative to standard culture techniques to establish substantial equivalence.

6. Physicians' Office studies were conducted to show that office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly. These studies were performed at three geographically distinct sites in the United States.

7. Stability studies are underway to establish the shelf-life of the product as well as its optimal storage and shipping conditions.

Conclusion:
These studies demonstrated the substantial equivalence of the CARDS Q.S. Strep A/Concise Performance Plus Strep A to existing products already marketed. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.