K961968

FEB - 4 1997

May 17, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	BBLCRYSTAL™ Gram Positive ID System
Common Name/Description:	Miniaturized Microorganism ID System
Classification Name:	Microbiology - Discs, Strips, and Reagents, Microorganism Differentiation

PREDICATE DEVICES:

BioMerieux Vitek, Inc., API Staph (K813614)
BioMerieux Vitek, Inc., API 20 Strep (K813610)
BioMerieux Vitek, Inc., API Coryne (K910304)

DEVICE DESCRIPTION:

INTENDED USE: The BBLCRYSTAL™ Gram Positive (GP) Identification (ID) System is a miniaturized identification method employing modified conventional, fluorogenic, and chromogenic substrates. It is intended for the identification of frequently isolated aerobic gram-positive bacteria from clinical specimens.

INDICATIONS FOR USE: Use of the BBLCRYSTAL™ Gram Positive Identification System is indicated when the aerobic gram-positive organisms described in the attached table have been isolated in pure culture from clinical specimens in a clinical laboratory, and identification of the microorganisms is desired.

TABLE B-I: Taxa List for BBLCRYSTAL™ Gram Positive Identification System

Actinomyces pyogenes
Aerococcus species(includes A. urinae and A. viridans)
Aerococcus urinae
Aerococcus viridans
Alloiococcus otitidis[1]
Arcanobacterium haemolyticum[1]

Bacillus brevis
Bacillus cereus
Bacillus circulans
Bacillus coagulans
Bacillus licheniformis
Bacillus megaterium
Bacillus pumilus
Bacillus species (includes B. brevis, B. circulans, B. coagulans, B. licheniformis, B. megaterium, B. pumilus and B. sphaericus, P. alvei, P. macerans)
Bacillus sphaericus
Bacillus subtilis

Corynebacterium aquaticum
Corynebacterium bovis
Corynebacterium diptheriae (includes C. diptheriae ssp gravis, C. diptheriae ssp mitis and C. diptheriae ssp intermedius
Corynebacterium genitalium
Corynebacterium jeikeium
Corynebacterium kutscheri
Corynebacterium propinquum
Corynebacterium pseudodiptheriticum
Corynebacterium pseudogenitalium
Corynebacterium pseudotuberculosis
Corynebacterium renale group
Corynebacterium species (includes C. aquaticum, C. bovis, C. kutscheri, C. propinquum, c. pseudodiphtheriticum, C. pseudotuberculosis, C. renale group, C. striatum and C. ulcerans)
Corynebacterium striatum
Corynebacterium ulcerans

Enterococcus avium
Enterococcus casseliflavus/gallinarum
Enterocuccus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus hirae
Enterococcus raffinosus
Enterocuccus solitarius
Erysipelothrix rhusiopathiae

Gardnerella vaginalis
Gemella haemolysans
Gemella morbillorum
Gemella species (includes G. haemolysans, and G. morbillorum)
Globicatella sanguis

Helcococcus kunzii

Lactococcus garvieae
Lactococcus lactis ssp cremoris
Lactococcus lactis ssp hordniae
Lactococcus lactis ssp lactis
Lactococcus raffinolactis
Lactococcus species (includes L. lactis ssp cremoris, L. lactis ssp hordniae, L. lactis ssp lactis and L. raffinolactis)
Leuconostoc citreum
Leuconostoc lactis
Leuconostoc mesenteroides ssp mesenteroides
Leuconostoc pseudomesenteroides
Leuconostoc species (includes L. citreum, L. lactis, L. mesenteroides ssp mesenteroides and L. pseudomesenteroides)
Listeria grayi[1]
Listeria ivanovii ssp ivanovii
Listeria monocytogenes
Listeria murrayi

Micrococcus kristinae
Micrococcus luteus
Micrococcus lylae
Micrococcus roseus
Micrococcus sedentarius
Micrococcus species (includes M. kristinae, M. luteus, M. lylae, M. roseus, M. sedentarius)

Oerskovia species (includes O. turbata, and O. xanthineolytica)

Paenibacillus alvei
Paenibacillus macerans
Pediococcus damnosus
Pediococcus parvulus
Pediococcus pentosaceus
Pediococcus species (includes P.damnosus, P. parvulus, and P. pentosaceus)

Rhodococcus equi
Rothia dentocariosa[1]

Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis (includes S. capitis ssp capitis and S. capitis ssp ureolyticus)
Staphylococcus caprae
Staphylococcus carnosus
Staphylococcus cohnii (includes S. cohnii ssp cohnii and S. cohnii ssp urealyticum)
Staphylococcus cohnii ssp cohnii
Staphylococcus cohnii ssp urealyticum
Staphylococcus epidermidis
Staphylococcus equorum
Staphylococcus felis
Staphylococcus gallinarum
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus intermedius
Staphylococcus kloosii
Staphylococcus lentus
Staphylococcus lugdunensis
Staphylococcus pasteuri[1]
Staphylococcus saccharolyticus
Staphylococcus saprophyticus
Staphylococcus schleiferi (includes S. schleiferi ssp cagulans and S. schleiferi ssp schleiferi)
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus vitulus
Staphylococcus warneri
Staphylococcus xylosus
Stomatococcus mucilaginosus
Streptococcus acidominimus
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus bovis (includes S. bovis I and S. bovis II)
Streptococcus constellatus
Streptococcus cricetus[1]
Streptococcus crista
Streptococcus dysgalactiae
Streptococcus equi (includes S. equi ssp equi and S. equi ssp zooepidemicus)
Streptococcus equi ssp equi
Streptococcus equi ssp zooepidemicus
Streptococcus equinus
Streptococcus gordonii
Streptococcus intermedius
Streptococcus milleri group (includes S. anginosus, S. constellatus and S. intermedius)
Streptococcus mitis
Streptococcus mitis group (includes S. mitis and S. oralis)
Streptococcus mutans
Streptococcus mutans group (includes S. cricetus, S. mutans and S. sobrinus)
Streptococcus oralis
Streptococcus parasanguis
Streptococcus pneumoniae
Streptococcus porcinus
Streptococcus pyogenes
Streptococcus salivarius
Streptococcus salivarius group (includes S. salivarius and S. vestibularis)
Streptococcus sanguis
Streptococcus sanguis group (includes S. crista, S. gordonii, S. parasanguis and S. sanguis)
Streptococcus sobrinus
Streptococcus uberis
Streptoccus vestibularis

Turicella otitidis[1]

[1] *These taxa have < 10 unique CRYSTAL profiles in the current database.*

PRODUCT DESCRIPTION:

The main component of the BBLCRYSTAL™ GP ID System is the BBLCRYSTAL GP panel assembly, consisting of the CRYSTAL base and lid. The BBLCRYSTAL lid consists of 29 dehydrated biochemical/chromogenic/ fluorogenic substrates and one fluorogenic negative control, on the ends of plastic prongs. The CRYSTAL base consists of 30 matching wells; its design allows inoculation of all 30 wells in a single step by pouring the suspension of pure culture into the target area and tilting the base. The test inoculum rehydrates the dried substrates and initiates test reactions.

The pure culture suspension is prepared by picking several small colonies of the same morphology from media such as Trypticase® Soy Agar with 5% Sheep Blood or Columbia Agar with 5% Sheep Blood, or alternatively selective media such as Phenylethyl Alcolol Agar with 5% Sheep Blood or Columbia CNA Agar with 5% Sheep Blood. A standardized suspension of this culture is prepared in the BBLCRYSTAL™ ANR, GP, RGP, N/H ID Inoculum Fluid provided. The suspension is added to the target area of the panel base, which the use then rocks back and forth to inoculate all the wells contained in the base.

After the base/lid assembly has been incubated for 4 hours at 35-37°C, the assembly is placed on the BBLCRYSTAL Panel Viewer and the color reactions are visually compared to the BBLCRYSTAL GP Color Chart provided. Each reaction is scored as a positive (+) or negative (-) and recorded on the BBLCRYSTAL GP Report Form.

After all results are read, a 10-digit numerical profile is calculated by assigning a value of 4, 2, or 1 to each positive reaction. (Negative reactions are scored as "0".) The values for each column are then added together to obtain the 10 digit Profile Number.

The BBLCRYSTAL ID System Electronic Codebook is loaded into the user's PC and the appropriate database is selected. Then the Profile Number and results of any off-line tests are entered, and the Codebook gives one of the following three results:

(a) a definitive ID;
(b) a tie between two or more species; or
(c) no ID possible with data submitted.

In the case of a definitive ID or a tie between two or more potential ID's, the user can access the statistics for that ID as well as background information for the species identified.

In the case where no ID is possible, the Codebook suggests that the user perform a purity check of the test isolate. If culture purity has been confirmed, then it is likely that (i) the test isolate is producing atypical Crystal reactions (which may also be caused by procedural errors), (ii) the test species is not part of the intended taxa, or (iii) the system is unable to identify the test isolate with the required level of confidence. Once user error has been ruled out, the Codebook suggests that additional testing must be done to establish an identification.

PERFORMANCE DATA:

Clinical Correlation:

In a study conducted at four clinical laboratories, the performance of the BBLCRYSTAL Gram Positive ID System was evaluated against a combination of the API Staph, API 20 Strep, and API Coryne Identification Systems, and conventional methodologies. Fresh, routine isolates arriving in the clinical laboratory, as well as previously identified isolates of the clinical trial sites' choice were utilized in the study. A total of 735 gram positive aerobic isolates were tested; 90% (668/735) of these isolates were correctly identified (including supplemental testing) using the BBLCRYSTAL™ GP ID System; 7.6% (56/735) were incorrectly identified; and 1.5% (11/735) yielded a "No Identification" result.

Reproducibility:

At the same four clinical laboratories, reproducibility of the BBLCRYSTAL™ GP ID System was established by testing ten (10) Quality Control strains in triplicate on three days. Evaluations were performed of individual and overall reproducibility of substrate reactions, of QC organism reactions, and of inter- and intra-laboratory reproducibility.

Overall reproducibility was calculated as 96.7%. Reproducibility of individual substrate reactions ranged from 79.2 to 100%; individual QC organism reaction reproducibility ranged from 91.4 to 99.8%; and individual site reproducibility from 95.5 to 97.8%.