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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	BBLCRYSTAL™ *Neisseria/Haemophilus* (N/H) ID System
Common Name/Description:	Miniaturized Microorganism ID System
Classification Name:	Microbiology - Discs, Strips, and Reagents, Microorganism Differentiation

PREDICATE DEVICES:

Innovative Diagnostic Systems, Inc., RapID™ NH System (K881501)

DEVICE DESCRIPTION:

INTENDED USE: The BBLCRYSTAL™ *Neisseria/Haemophilus* (N/H) Identification (ID) System is a miniaturized identification method employing modified conventional, fluorogenic, and chromogenic substrates. It is intended for the identification of frequently isolated *Neisseria* and *Haemophilus* as well as several other fastidious bacteria from clinical specimens.

INDICATIONS FOR USE: Use of this product is indicated when *Neisseria, Haemophilus* and the other fastidious organisms described in Table B-I 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™ *Neisseria/Haemophilus* (N/H) Identification System

Actinobacillus actinomycetemcomitans

Cardiobacterium hominis[1]

Eikenella corrodens

Gardnerella vaginalis

Haemophilus aphrophilus/paraphrophilus

Haemophilus ducreyi

Haemophilus haemoglobinophilus[1]

Haemophilus haemolyticus

Haemophilus influenzae (includes *H. influenzae* biogroup *aegyptius*, *H. influenzae* biotype I, *H. influenzae* biotype II, *H. influenzae* biotype III, *H. influenzae* biotype IV, *H. influenzae* biotype V, *H. influenzae* biotype VI and *H. influenzae* biotype VIII)

Haemophilus parahaemolyticus[1]

Haemophilus parainfluenzae (includes *H. parainfluenzae* biotype I, *H. parainfluenzae* biotype II, *H. parainfluenzae* biotype III, and *H. parainfluenzae* biotype IV)

Haemophilus segnis[1]

Kingella denitrificans

Kingella kingae

Kingella species (includes *K. denitrificans* and *K. kingae*)

Moraxella atlantae

Moraxella (Branhamella) catarrhalis

Moraxella lacunata[1]

Moraxella nonliquefaciens

Moraxella osloensis

Moraxella phenylpyruvica[1]

Moraxella species (includes *M. atlantae*, *M. lacunata*, *M. nonliquefaciens*, *M. osloensis* and *M. phenylpyruvica*)

Neisseria cinerea[1]

Neisseria elongata (includes *N. elongata* ssp. *elongata*, *N. elongata* ssp. *glycolytica* and *N. elongata* ssp. *nitroreducens*)

Neisseria flavescens[1]

Neisseria gonorrhoeae

Neisseria lactamica

Neisseria meningitidis

Neisseria mucosa

Neisseria sicca

Neisseria subflava (includes *N. subflava* biovar *flava*, *N. subflava* biovar *perflava* and *N. subflava* biovar *subflava*)

Neisseria weaveri[1]

Oligella species (includes *O. urethralis* and *O. ureolytica*)

Oligella ureolytica[1]

Oligella urethralis

Pasteurella multocida

Suttonella indologenes

[1] These taxa have fewer than 10 unique BBLCRYSTAL profiles in the current database.

PRODUCT DESCRIPTION:

The main component of the BBLCRYSTAL™ N/H ID System is the BBLCRYSTAL N/H 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 Chocolate Agar, Trypticase® Soy Agar with 5% Sheep Blood, Columbia Agar with 5% Sheep Blood, and Nutrient Agar, or alternatively, selective media such as Martin Lewis Agar, Thayer-Martin Modified Agar, New York City Medium Modified, V Agar, and GC-Lect® Agar. 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 N/H Color Chart provided. Each reaction is scored as a positive (+) or negative (-) and recorded on the BBLCRYSTAL N/H 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 BBLCRYSTAL 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 three clinical laboratories, the performance of the BBLCRYSTAL *Neisseria/Haemophilus* (N/H) ID System was evaluated against the RapID™ NH System 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 513 isolates were tested; 93.6% (480) of these isolates were correctly identified (including supplemental testing) using the BBLCRYSTAL™ N/H ID System; 5.1% (26) were incorrectly identified; and 1.4% (7) yielded a "No Identification" result.

Reproducibility:

At the same three clinical laboratories, reproducibility of the BBLCRYSTAL™ N/H 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 95.9%. Reproducibility of individual substrate reactions ranged from 85.7 to 100%; individual QC organism reaction reproducibility ranged from 87.7% to 99.2%; and site reproducibility ranged from 95.2% to 97.2%.