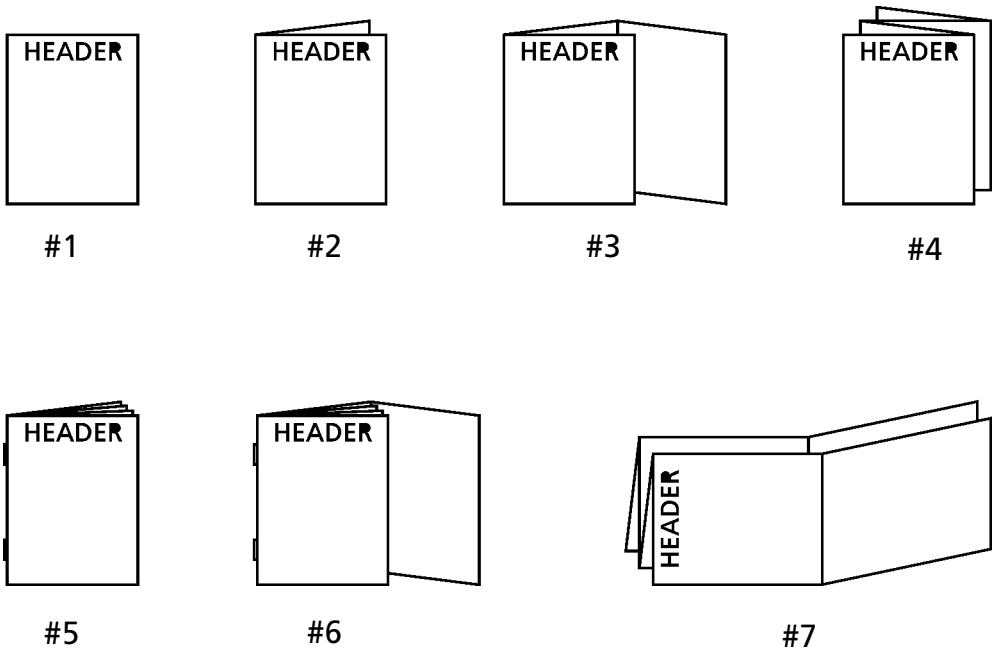
Revisions

Rev from	Rev to	ECO #
0602	**0404**	**2771-04**

Notes:

1. BD Cat. Number 245240
2. Blank (Sheet) Size : Length: 8.5” Width: 11”
   Number of Pages: 16 Number of Sheets: 8
   Page Size: Length 8.5” Width 5.5” Final Folded Size: 8.5” x 5.5”
3. Style (see illustrations below): # 5



4. See Specification Control Number 8809911 for Material Information
5. Ink Colors: Printed two sides ☒ Yes ☐ No
   No. of Colors: 1 PMS# 513 Purple
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level

Label Design Date Proofer Date Checked By Date Part Number: 8809911JAA		BD Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA	
	Category and Description Package Insert, BBL Crystal GP ID Kit	Sheet: 1 of 13 Scale: N/A	A

BD BBL Crystal™ Identification Systems
Gram-Positive ID Kit

8809911JAA
2004/04

CLIA COMPLEXITY: HIGH
CDC IDENTIFIER CODES
ANALYTE: 0412
TEST SYSTEM: 07919

U.S. Pat. 5,182,082
U.S. Pat. 5,338,666

See symbol glossary at end of insert.

INTENDED USE

The **BBL Crystal™** 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 aerobic gram-positive bacteria.[1,2,13,16]

SUMMARY AND EXPLANATION

Micromethods for the biochemical identification of microorganisms were reported as early as 1918.[3] Several publications reported on the use of the reagent-impregnated paper discs and micro-tube methods for differentiating enteric bacteria.[3,4,7,17,19] The interest in miniaturized identification systems led to the introduction of several commercial systems in the late 1960s, and they provided advantages in requiring little storage space, extended shelf life, standardized quality control and ease of use.

In general, many of the tests used in the **BBL Crystal** ID Systems are modifications of classical methods. These include tests for fermentation, oxidation, degradation and hydrolysis of various substrates. In addition, there are chromogen and fluorogen linked substrates, as in the **BBL Crystal** GP ID panel, to detect enzymes that microbes use to metabolize various substrates.[5,7,8,9,11,12,14,15]

The **BBL Crystal** GP ID kit is comprised of (i) **BBL Crystal** GP ID panel lids, (ii) **BBL Crystal** bases and (iii) **BBL Crystal** ANR, GP, RGP, N/H ID Inoculum Fluid (IF) tubes. The lid contains 29 dehydrated substrates and a fluorescence control on tips of plastic prongs. The base has 30 reaction wells. Test inoculum is prepared with the inoculum fluid and is used to fill all 30 wells in the base. When the lid is aligned with the base and snapped in place, the test inoculum rehydrates the dried substrates and initiates test reactions.

Following an incubation period, the wells are examined for color changes or presence of fluorescence that result from metabolic activities of the microorganisms. The resulting pattern of the 29 reactions is converted into a ten-digit profile number that is used as the basis for identification.[18] Biochemical and enzymatic reaction patterns for the 29 **BBL Crystal** GP ID substrates for a wide variety of microorganisms are stored in the **BBL Crystal** GP ID data base. Identification is derived from a comparative analysis of the reaction pattern of the test isolate to those held in the database. A complete list of taxa that comprises the current database is provided in **Table 1** (*see pg. 7*).

PRINCIPLES OF THE PROCEDURE

The **BBL Crystal** GP ID panels contain 29 dried biochemical and enzymatic substrates. A bacterial suspension in the inoculum fluid is used for rehydration of the substrates. The tests used in the system are based on microbial utilization and degradation of specific substrates detected by various indicator systems. Enzymatic hydrolysis of fluorogenic substrates containing coumarin derivatives of 4-methylumbelliferone (4MU) or 7-amino-4-methylcoumarin (7-AMC), results in increased fluorescence that is easily detected visually with a UV light source.[11,12,14,15] Chromogenic substrates upon hydrolysis produce color changes that can be detected visually. In addition, there are tests that detect the ability of an organism to hydrolyze, degrade, reduce or otherwise utilize a substrate in the **BBL Crystal** ID Systems.

Reactions employed by various substrates and a brief explanation of the principles employed in the system are described in **Table 2** (*see pg. 8*). Panel location in referred tables indicates the row and column where the well is located (example: 1J refers to Row 1 in column J).

REAGENTS

The **BBL Crystal** GP ID panel contains 29 enzymatic and biochemical substrates. Refer to **Table 3** (*see pg. 9*) for a list of active ingredients.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

After review by the U.S. Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) under CLIA '88, this product has been identified as high complexity. The CDC Analyte Identifier Code is 0412; the CDC Test System Identifier Code is 07919.

After use, all infectious materials including plates, cotton swabs, inoculum fluid tubes, and panels must be autoclaved prior to disposal or incineration.

STORAGE AND HANDLING/SHELF LIFE

Lids: BBL Crystal GP lids are individually packaged and must be stored unopened in a refrigerator at 2–8°C. DO NOT FREEZE. Visually inspect the package for holes or cracks in the foil package. Do not use if the packaging appears to be damaged. Lids in the original packaging, if stored as recommended, will retain expected reactivity until the date of expiration.

Bases: Bases are packaged in two sets of ten, in **BBL Crystal** incubation trays. The bases are stacked facing down to minimize air contamination. Store in a dust-free environment at 2–30°C, until ready to use. Store unused bases in the tray, in plastic bag. Empty trays should be used to incubate inoculated panels.

Inoculum Fluid: BBL Crystal ANR, GP, RGP, N/H ID Inoculum Fluid (IF) is packaged in two sets of ten tubes. Visually inspect the tubes for cracks, leaks, etc. Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity). Store tubes at 2–25°C. Expiration dating is shown on the tube label. Only ANR, GP, RGP, N/H Inoculum Fluid should be used with **BBL Crystal** GP ID panels.

On receipt, store the **BBL Crystal** GP ID kit at 2–8°C. Once opened, only the lids need to be stored at 2–8°C. The remaining components of the kit may be stored at 2–25°C. If the kit or any of the components are stored refrigerated, each should be brought to room temperature prior to use.

SPECIMEN COLLECTION AND PROCESSING

BBL Crystal ID Systems are not for use directly with clinical specimens. Use isolates from media such as **Trypticase™** Soy Agar with 5% Sheep Blood (TSA II) or Columbia Agar with 5% Sheep Blood (Columbia Blood Agar). Use of selective media such as Phenylethyl Alcohol Agar with 5% Sheep Blood (PEA) or Columbia CNA Agar with 5% Sheep Blood (CNA) is also acceptable. Media containing esculin should not be used. The test isolate must be a pure culture, no more than 18–24 h old for most genera; for some slow growing organisms up to 48 h may be acceptable. When swabs are utilized, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels. (See "Limitations of the Procedure").

The incubator used should be humidified to prevent evaporation of fluid from the wells during incubation. The recommended humidity level is 40–60%. The usefulness of **BBL Crystal** ID Systems or any other diagnostic procedure performed on clinical specimens is directly influenced by the quality of the specimens themselves. It is strongly recommended that laboratories employ methods discussed in the *Manual of Clinical Microbiology* for specimen collection, transport and inoculation onto primary isolation media.[1,16]

TEST PROCEDURE

Materials Provided: BBL Crystal GP ID Kit –

20 **BBL Crystal** GP ID Panel Lids,

20 **BBL Crystal** Bases,

20 **BBL Crystal** ANR, GP, RGP, N/H ID IF Tubes. Each tube has approximately 2.3 ± 0.15 mL of Inoculum Fluid containing: KCl 7.5 g, $CaCl_2$ 0.5 g, Tricine N-[2-Hydroxy-1, 1-bis (hydroxymethyl)methyl] glycine 0.895 g, purified water to 1000 mL,

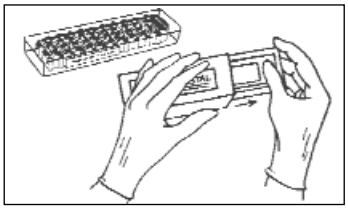
2 incubation trays,

1 **BBL Crystal** GP ID Color Reaction Chart and Results Pad.

Materials Required But Not Provided: Sterile cotton swabs (*do not use polyester swabs*), incubator (35 – 37°C) non-CO_2 (40–60% humidity), McFarland No. 0.5 standard, **BBL Crystal** Panel Viewer, **BBL Crystal** ID System Electronic Codebook or **BBL Crystal** Gram-Positive Manual Codebook, and appropriate culture media.

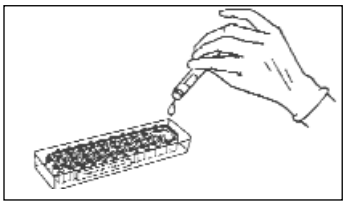
Also required are the necessary equipment and labware used for preparation, storage and handling of clinical specimens.

Test Procedure: BBL Crystal GP ID System requires a Gram stain.

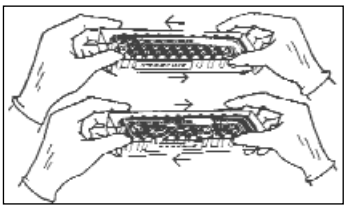


1. Remove lids from pouch. Discard desiccant. Once removed from the pouch, covered lids should be used within 1 h. Do not use the panel if there is no desiccant in the pouch.
2. Take an inoculum fluid tube and label with patient's specimen number. Using aseptic technique, pick colonies of the same morphology with the tip of a sterile cotton swab (*do not use a polyester swab*) or a wooden applicator stick from one of the recommended media (see section under "Specimen Collection and Processing").
3. Suspend colonies in a tube of **BBL Crystal** ANR, GP, RGP, N/H ID Inoculum Fluid.
4. Recap tube and vortex for approximately 10–15 s. The turbidity should be equivalent to a McFarland No. 0.5 standard. If the inoculum suspension concentration is in excess of the recommended McFarland standard, one of the following steps is recommended:
   a. Use a fresh tube of inoculum fluid to prepare a new inoculum suspension equivalent to a McFarland No. 0.5 standard.
   b. If additional colonies are unavailable for preparation of a new inoculum suspension, using aseptic techniques, dilute the inoculum by adding the minimum required volume (not to exceed 1.0 mL) of 0.85% sterile saline or inoculum fluid to bring down the turbidity equivalent to a McFarland No. 0.5 standard. Remove the excess amount added to the tube with a sterile pipet so that the final volume of inoculum fluid is approximately equivalent to that of the original volume in the tube (2.3 ± 0.15 mL). Failure to make this adjustment in volume will result in spilling of the inoculum suspension over the black portion of the base rendering the panel unusable.

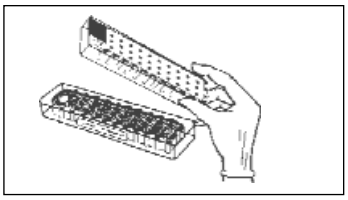
5. Take a base, and mark the patient's specimen number on the side wall.
6. Pour entire contents of the inoculum fluid tube into target area of the base.



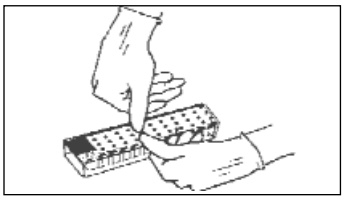
7. Hold base in both hands and roll inoculum gently along the tracks until all of the wells are filled. Roll *back* any excess fluid to the target area and place the base on a bench top.



8. Align the lid so that the labeled end of the lid is on top of the target area of the base.

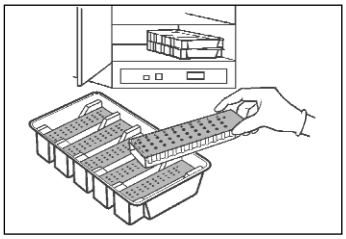


9. Push down until a slight resistance is felt. Place thumb on edge of lid towards middle of panel on each side and push downwards simultaneously until the lid snaps into place (listen for two "clicks").

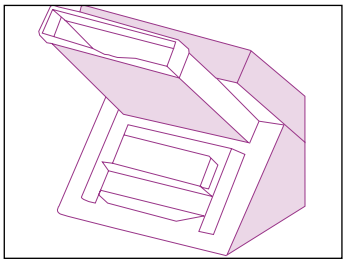


Purity Plate: Using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the base and inoculate an agar slant or plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the slant or plate for 24–48 h at 35–37°C under appropriate conditions. The purity plate or slant may also be used for any supplementary tests or serology, if required.

Incubation: Place inoculated panels in incubation trays. Ten panels can fit in one tray (5 rows of 2 panels). All panels should be incubated **face down** (larger windows facing up; label facing down) in a non-CO_2 incubator with 40–60% **humidity**. Trays should not be stacked more than two high during incubation. The incubation time for panels is 18–24 h at 35–37°C. If panels are incubated for 24 h, they should be read within 30 min after removing from incubator.



Reading: After the recommended period of incubation, remove the panels from the incubator. All panels should be read **face down** (larger windows up; label facing down) using the **BBL Crystal** Panel Viewer. Refer to the color reaction chart and/or **Table 3** (*see pg. 9*) for an interpretation of the reactions. Use the results pad to record reactions. Alternatively, the **BBL Crystal** AutoReader may be used to read the panels.



a. Read columns E thru J first, using the regular (white) light source.

b. Read columns A thru D (fluorescent substrates) using the UV light source in the panel viewer. A fluorescent substrate well is considered positive *only* if the intensity of the fluorescence observed in the well is *greater* than the Negative Control well (4A).

Calculation of BBL Crystal Profile Number: Each test result (except 4A, which is used as a fluorescence negative control) scored positive is given a value of 4, 2, or 1, corresponding to the row where the test is located. A value

of 0 (zero) is given to any negative result. The values resulting from each positive reaction in each column are then added together. A 10-digit number is generated; this is the profile number.

Example:	A	B	C	D	E	F	G	H	I	J
4	*	+	-	-	+	+	+	-	+	-
2	-	+	+	+	-	+	-	+	+	-
1	+	-	+	-	+	-	-	+	+	-
Profile	**1**	**6**	**3**	**2**	**5**	**6**	**4**	**3**	**7**	**0**

*(4A) = fluorescent negative control

The resulting profile number and cell morphology, if known, should be entered on a PC in which the **BBL Crystal** Mind Software has been installed to obtain the identification. If using the **BBL Crystal** AutoReader, organisms are automatically identified by the PC. A manual codebook is also available. If a PC is not available contact BD Technical Services for assistance with the identification.

User Quality Control: Quality control testing is recommended for each lot of panels as follows –

1. Inoculate a panel with *Streptococcus pyogenes* ATCC™ 19615 per recommended procedure (refer to "Test Procedure").
2. Incubate panel for 18–20 h at 35–37°C.
3. Read panel with the panel viewer and color reaction chart; record reactions using the results pad. Alternatively, read the panel on the **BBL Crystal** AutoReader.
4. Compare recorded reactions with those listed in **Table 4** (*see pg. 10*). If discrepant results are obtained, confirm purity of quality control strain before contacting BD Technical Services.

Expected test results for additional quality control test strains are listed in **Table 5** (*see pg. 10*).

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent NCCLS guidance and CLIA regulations for appropriate Quality Control practices.

LIMITATIONS OF THE PROCEDURE

The **BBL Crystal** GP ID System is designed for the taxa provided. Taxa other than those listed in Table 1 are not intended for use in this system.

The **BBL Crystal** GP ID System database includes some species that are rarely isolated from human clinical specimens and were not encountered in the clinical studies of this product. It also includes some species that were encountered less than 10 times in the clinical studies. Refer to **Table 1** (*see pg. 7*) for a breakdown of the number of strains per species tested in clinical trials. The laboratorian should determine if additional testing is required to confirm identity of those species for which performance has not been established (i.e., those species where less than 10 isolates were evaluated in the clinical trials for this product).

The **BBL Crystal** GP ID database was developed with **BBL**™ brand media. Reactivity of some substrates in miniaturized identification systems may be dependent upon the source media used in inoculum preparations. We recommend the use of the following media for use with the **BBL Crystal** GP ID System: TSA II and Columbia Blood Agar. Use of selective media, such as PEA or CNA is also acceptable. Media containing esculin should not be used.

BBL Crystal Identification Systems use a modified microenvironment; therefore, expected values for its individual tests may differ from information previously established with conventional test reactions. The accuracy of the **BBL Crystal** GP ID System is based on statistical use of specially designed tests and an exclusive database.

While **BBL Crystal** GP ID System aids in microbial differentiation, it should be recognized that minor variations may exist in strains within species. Use of panels and interpretation of results require a competent microbiologist. The final identification of the isolate should take into consideration the source of the specimen, aerotolerance, cell morphology, colonial characteristics on various media as well as metabolic end products as determined by gas-liquid chromatography, when warranted.

Only cotton-tipped applicator swabs should be used to prepare the inoculum suspension as some polyester swabs may cause the inoculum fluid to become viscous. This may result in insufficient inoculum fluid to fill the wells. Covered lids once removed from the sealed pouches must be used within 1 h to ensure adequate performance.

The incubator where panels are placed should be humidified to prevent evaporation of inoculum fluid from the wells during incubation. The recommended humidity level is 40–60%.

The panels, after inoculation, should only be incubated face down (larger windows facing up; label facing down) to maximize the effectiveness of substrates.

If the **BBL Crystal** test profile yields a "No identification" result and culture purity has been confirmed, then it is likely that (i) the test isolate is producing *atypical* **BBL 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. Conventional test methods are recommended when user error has been ruled out.

EXPECTED VALUES

The expected substrate reactions for the species of organisms most frequently encountered in the clinical study of **BBL Crystal** GP ID System are shown in **Table 6** (*see pg. 11*). The provided percentages were generated from reactions given by the organisms used in generating the database. **Table 1** (*see pg. 7*) shows all the taxa tested during database generation.

PERFORMANCE CHARACTERISTICS

Reproducibility: In an external study involving four clinical laboratories, (total of four evaluations), the reproducibility of **BBL Crystal** GP ID substrates' (29) reactions was studied by replicate testing. The reproducibility of the individual substrate reactions ranged from 79.2%–100%. The overall reproducibility of **BBL Crystal** GP ID panel was determined to be 96.7%.[20]

Accuracy of Identification: The performance of **BBL Crystal** GP ID System was compared to currently available commercial systems using clinical isolates and stock cultures. A total of four studies were conducted in four independent laboratories. Fresh, routine isolates arriving in the clinical laboratory, as well as previously identified isolates of the clinical trial sites' choice, were utilized to establish performance characteristics.

Out of 735 total isolates tested from the four studies using **BBL Crystal** GP Identification System, 623 (84.8%) were correctly identified without the use of supplement tests, and 668 (90.9%) were correctly identified when supplemental tests were included. A total of 56 (7.6%) isolates were incorrectly identified, and a message of "No Identification" was obtained for 11 (1.5%) isolates.[20] **Table 7** (*see pg. 12*) shows the acccuracy of identification for the species most frequently encountered (i.e., 10 or more isolates) in the clinical trial as well as for the remaining group of species where less than 10 isolates were tested.

AVAILABILITY

Cat. No.	Description
245240	**BBL Crystal™** Gram-Positive ID Kit, containing 20 each: **BBL Crystal** GP ID Panel Lids, **BBL Crystal** Bases and **BBL Crystal** ANR, GP, RGP, N/H ID Inoculum Fluid.
245038	**BBL Crystal™** ANR, GP, RGP, N/H ID Inoculum Fluid, ctn. of 10.
245031	**BBL Crystal™** Panel Viewer, Domestic model, 110 V, 60 Hz.
245032	**BBL Crystal™** Panel Viewer, European model, 220 V, 50 Hz.
245033	**BBL Crystal™** Panel Viewer, Japanese model, 100 V, 50/60 Hz.
245034	**BBL Crystal™** Panel Viewer, Longwave UV Tube.
245036	**BBL Crystal™** Panel Viewer, White Light Tube.
245037	**BBL Crystal™** Identification Systems Gram-Positive Manual Codebook.
441010	**BBL Crystal™** Mind Software
245300	**BBL Crystal™** AutoReader
221165	**BBL™** Columbia Agar with 5% Sheep Blood, pkg. of 20.
221263	**BBL™** Columbia Agar with 5% Sheep Blood, ctn. of 100.
221352	**BBL™** Columbia CNA Agar with 5% Sheep Blood, pkg. of 20.
221353	**BBL™** Columbia CNA Agar with 5% Sheep Blood, ctn. of 100.
221179	**BBL™** Phenylethyl Alcohol Agar with 5% Sheep Blood, pkg. of 20.
221277	**BBL™** Phenylethyl Alcohol Agar with 5% Sheep Blood, ctn. of 100.
221239	**BBL™ Trypticase™** Soy Agar with 5% Sheep Blood (TSA II), pkg. of 20.
221261	**BBL™ Trypticase™** Soy Agar with 5% Sheep Blood (TSA II), ctn. of 100.
212539	**BBL™** Gram Stain Kit, pkg. of 4 x 250 mL bottles.

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20. Data on file at BD Diagnostics.

Key: Table 1

KEY: * = These taxa have fewer than 10 unique **BBL Crystal** profiles in the current database.
("x") = Number of isolates (i.e., "x") encountered in the clinical trial. If no number in parenthesis is shown after an organism name or group description, these species were not encountered in the clinical trial.

Note #1: There were 14 additional isolates encountered in the clinical trial that are not shown above. Five (5) (i.e., 4 *Staphylococcus* species and 1 *Enterococcus* were identified only to the genus level by the reference system against which **BBL Crystal** GP was compared, although **BBL Crystal** GP identified these organisms to the species level. Nine (9) were identifed by the reference system, but were not included in the **BBL Crystal** GP database taxa.

Note #2: The organisms shown in bold face type were encountered 10 or more times in the clinical study for this product.

Note #3: The organisms not shown in bold face type are either species which are rarely isolated from human clinical specimens or species that were infrequently (less than 10) encountered in the clinical study for this product. The laboratorian should determine if additional testing is required to confirm their identity.

Table 1
Taxa in BBL Crystal™ GP ID System

Actinomyces pyogenes
Aerococcus species (includes *A. urinae* and *A. viridans*)
Aerococcus urinae
Aerococcus viridans
Alloiococcus otitidis *
*Arcanobacterium haemolyticum**(2)
Bacillus brevis (1)
Bacillus cereus (2)
Bacillus circulans
Bacillus coagulans
Bacillus licheniformis (1)
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*) (9)
Bacillus sphaericus
Bacillus subtilis (1)
Corynebacterium aquaticum
Corynebacterium bovis
Corynebacterium diphtheriae (includes *C. diphtheriae* subsp *gravis, C. diphtheriae* subsp *mitis* and *C. diphtheriae* subsp *intermedius*)
Corynebacterium genitalium
Corynebacterium jeikeium (7)
Corynebacterium kutscheri
Corynebacterium propinquum (1)
Corynebacterium pseudodiphtheriticum (2)
Corynebacterium pseudogenitalium
Corynebacterium pseudotuberculosis (2)
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*) (29)**
Corynebacterium striatum (6)
Corynebacterium ulcerans
Enterococcus avium (3)
***Enterococcus casseliflavus/gallinarum* (14)**
Enterococcus durans (2)
***Enterococcus faecalis* (78)**
***Enterococcus faecium* (33)**
Enterococcus hirae
Enterococcus raffinosus (3)
Enterococcus solitarius
Erysipelothrix rhusiopathiae
Gardnerella vaginalis
Gemella haemolysans
Gemella morbillorum
Gemella species (includes *G. haemolysans* and *G. morbillorum*)
Globicatella sanguis (3)
Helcococcus kunzii
Lactococcus garvieae
Lactococcus lactis subsp *cremoris*
Lactococcus lactis subsp *hordniae*
Lactococcus lactis subsp *lactis*
Lactococcus raffinolactis
Lactococcus species (includes *L. lactis* subsp *cremoris, L. lactis* subsp *hordniae, L. lactis* subsp *lactis* and *L. raffinolactis*)
Leuconostoc citreum
Leuconostoc lactis (1)
Leuconostoc mesenteroides subsp *mesenteroides*
Leuconostoc pseudomesenteroides
Leuconostoc species (includes *L. citreum, L. lactis, L. mesenteroides* subsp *mesenteroides* and *L. pseudomesenteroides*)
Listeria grayi *
Listeria ivanovii subsp *ivanovii*
Listeria monocytogenes (3)
Listeria murrayi
Micrococcus kristinae
Micrococcus luteus
Micrococcus lylae
Micrococcus roseus
Micrococcus sedentarius
***Micrococcus* species (includes *M. kristinae, M. luteus, M. lylae, M. roseus* and *M. sedentarius*) (10)**
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* (88)**
Staphylococcus auricularis (2)
***Staphylococcus capitis* (includes *S. capitis* subsp *capitis* and *S. capitis* subsp *ureolyticus*) (13)**
Staphylococcus caprae
Staphylococcus carnosus
Staphylococcus cohnii (includes *S. cohnii* subsp *cohnii* and *S. cohnii* subsp *urealyticum*) (1)
Staphylococcus cohnii subsp *cohnii*
Staphylococcus cohnii subsp *urealyticum*
***Staphylococcus epidermidis* (88)**
Staphylococcus equorum
Staphylococcus felis
Staphylococcus gallinarum
***Staphylococcus haemolyticus* (23)**
***Staphylococcus hominis* (17)**
Staphylococcus intermedius
Staphylococcus kloosii (2)
Staphylococcus lentus
Staphylococcus lugdunensis (3)
*Staphylococcus pasteuri **(1)
Staphylococcus saccharolyticus (6)
Staphylococcus saprophyticus
Staphylococcus schleiferi (includes *S. schleiferi* subsp *coagulans* and *S. schleiferi* subsp *schleiferi*)
Staphylococcus sciuri
Staphylococcus simulans (3)
Staphylococcus vitulus
Staphylococcus warneri (6)
Staphylococcus xylosus (1)
Stomatococcus mucilaginosus (6)
Streptococcus acidominimus
***Streptococcus agalactiae* (54)**
Streptococcus anginosus (1)
***Streptococcus bovis* (includes *S. bovis* I and *S. bovis* II) (10)**
Streptococcus constellatus (1)
Streptococcus cricetus *
Streptococcus crista
Streptococcus equi (includes *S. equi* subsp *equi* and *S. equi* subsp *zooepidemicus*) (1)
Streptococcus equi subsp *equi* (2)
Streptococcus equi subsp *zooepidemicus*
Streptococcus equinus
Streptococcus gordonii
***Streptococcus* Group C/G (11)**
Streptococcus intermedius
***Streptococcus milleri* group (includes *S. anginosus, S constellatus* and *S. intermedius*) (20)**
Streptococcus mitis (4)
***Streptococcus mitis* group (includes *S. mitis* and *S. oralis*) (20)**
Streptococcus mutans
Streptococcus mutans group (includes *S. cricetus, S. mutans* and *S. sobrinus*) (2)
Streptococcus oralis
Streptococcus parasanguis (1)
***Streptococcus pneumoniae* (54)**
Streptococcus porcinus
***Streptococcus pyogenes* (50)**
Streptococcus salivarius (3)
Streptococcus salivarius group (includes *S. salivarius* and *S. vestibularis*) (4)
Streptococcus sanguis (2)
Streptococcus sanguis group (includes *S. crista, S. gordonii, S. parasanguis* and *S. sanguis*)
Streptococcus sobrinus
Streptococcus uberis
Streptococcus vestibularis
Turicella otitidis *

Table 2

Principles of Tests Employed in the BBL Crystal™ GP ID System

Panel Location	Test Feature	Code	Principle (Reference)
4A	Fluorescent negative control	FCT	Control to standardize fluorescent substrate results.
2A	4MU-β-D-glucoside	FGC	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin derivative.[5,8,11,12,14,15]
1A	L-valine-AMC	FVA	
4B	L-phenylalanine-AMC	FPH	
2B	4MU-α-D-glucoside	FGS	
1B	L-pyroglutamic acid-AMC	FPY	
4C	L-tryptophan-AMC	FTR	
2C	L-arginine-AMC	FAR	
1C	4MU-N-acetyl-β-D-glucosaminide	FGA	
4D	4MU-phosphate	FHO	
2D	4MU-β-D-glucuronide	FGN	
1D	L-isoleucine-AMC	FIS	
4E	Trehalose	TRE	Utilization of carbohydrate results in lower pH and change in indicator (Phenol red).[1,2,3,4,7,16]
2E	Lactose	LAC	
1E	Methyl-α & β-glucoside	MAB	
4F	Sucrose	SUC	
2F	Mannitol	MNT	
1F	Maltotriose	MTT	
4G	Arabinose	ARA	
2G	Glycerol	GLR	
1G	Fructose	FRU	
4H	p-nitrophenyl-β-D-glucoside	BGL	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.[5,9,12]
2H	p-nitrophenyl-β-D-cellobioside	PCE	
1H	Proline & Leucine-p-nitroanilide	PLN	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroaniline.[5,9,12]
4I	p-nitrophenyl-phosphate	PHO	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.[5,9,12]
2I	p-nitrophenyl-α-D-maltoside	PAM	
1I	o-nitrophenyl-β-D-galactoside (ONPG) & p-nitrophenyl-α-D-galactoside	PGO	
4J	Urea	URE	Hydrolysis of urea and the resulting ammonia change the pH indicator color (Bromthymol blue).[2,6,10]
2J	Esculin	ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.[10]
1J	Arginine	ARG	Utilization of arginine results in pH rise and change in the color of the indicator (Bromcresol purple).[2]

Table 3

Reagents used in the BBL Crystal™ GP ID System

Panel Location	Substrate	Code	Pos.	Neg.	Active Ingredients	Approx. Amt. (g/L)
4A	Fluorescent negative control	FCT	n/a	n/a	Fluorescent coumarin derivative	≤1
2A	4MU-β-D-glucoside	FGC	blue fluorescence >FCT well	blue fluorescence ≤FCT well	4MU-β-D-glucoside	≤1
1A	L-valine-AMC	FVA	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-valine-AMC	≤1
4B	L-phenylalanine-AMC	FPH	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-phenylalanine-AMC	≤1
2B	4MU-α-D-glucoside	FGS	blue fluorescence >FCT well	blue fluorescence ≤FCT well	4MU-α-D-glucoside	≤1
1B	L-pyroglutamic acid-AMC	FPY	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-pyroglutamic acid-AMC	≤1
4C	L-tryptophan-AMC	FTR	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-tryptophan-AMC	≤1
2C	L-arginine-AMC	FAR	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-arginine-AMC	≤1
1C	4MU-N-acetyl-β-D-glucosaminide	FGA	blue fluorescence >FCT well	blue fluorescence ≤FCT well	4MU-N-acetyl-β-D-glucosaminide	≤1
4D	4MU-phosphate	FHO	blue fluorescence >FCT well	blue fluorescence ≤FCT well	4MU-phosphate	≤1
2D	4MU-β-D-glucuronide	FGN	blue fluorescence >FCT well	blue fluorescence ≤FCT well	4MU-β-D-glucuronide	≤1
1D	L-isoleucine-AMC	FIS	blue fluorescence >FCT well	blue fluorescence ≤FCT well	L-isoleucine-AMC	≤1
4E	Trehalose	TRE	Gold/Yellow	Orange/Red	Trehalose	≤300
2E	Lactose	LAC	Gold/Yellow	Orange/Red	Lactose	≤300
1E	Methyl-α & β-glucoside	MAB	Gold/Yellow	Orange/Red	Methyl-α & β-glucoside	≤300
4F	Sucrose	SUC	Gold/Yellow	Orange/Red	Sucrose	≤300
2F	Mannitol	MNT	Gold/Yellow	Orange/Red	Mannitol	≤300
1F	Maltotriose	MTT	Gold/Yellow	Orange/Red	Maltotriose	≤300
4G	Arabinose	ARA	Gold/Yellow	Orange/Red	Arabinose	≤300
2G	Glycerol	GLR	Gold/Yellow	Orange/Red	Glycerol	≤300
1G	Fructose	FRU	Gold/Yellow	Orange/Red	Fructose	≤300
4H	p-n-p-β-D-glucoside	BGL	Yellow	Colorless	p-n-p-β-D-glucoside	≤10
2H	p-n-p-β-D-cellobioside	PCE	Yellow	Colorless	p-n-p-β-D-cellobioside	≤10
1H	Proline & Leucine-p-nitroanilide	PLN	Yellow	Colorless	Proline & Leucine-p-nitroanilide	≤10
4I	p-n-p-phosphate	PHO	Yellow	Colorless	p-n-p-phosphate	≤10
2I	p-n-p-α-D-maltoside	PAM	Yellow	Colorless	p-n-p-α-D-maltoside	≤10
1I	ONPG & p-n-p-α-D-galactoside	PGO	Yellow	Colorless	ONPG & p-n-p-α-D-galactoside	≤10
4J	Urea	URE	Aqua/Blue	Yellow/Green	Urea	≤50
2J	Esculin	ESC	Brown/Maroon	Clear/Tan	Esculin	≤25
1J	Arginine	ARG	Purple	Yellow/Gray	Arginine	≤200

Table 4
Quality Control Chart for BBL Crystal™ GP ID System
After 18–20 Hours Incubation from TSA II or Columbia Blood Agar

Panel Location	Substrate	Code	*Streptococcus pyogenes* ATCC 19615
4A	Fluorescent negative control	FCT	-
2A	4 MU-β-D-glucoside	FGC	-
1A	L-valine-AMC	FVA	+
4B	L-phenylalanine-AMC	FPH	+
2B	4MU-α-D-glucoside	FGS	+
1B	L-pyroglutamic acid -AMC	FPY	+
4C	L-tryptophan-AMC	FTR	+
2C	L-arginine-AMC	FAR	+
1C	4MU-N-acetyl-β-D-glucosaminide	FGA	-
4D	4MU-phosphate	FHO	+
2D	4MU-β-D-glucuronide	FGN	-
1D	L-isoleucine-AMC	FIS	+
4E	Trehalose	TRE	+
2E	Lactose	LAC	+
1E	Methyl-α & β-glucoside	MAB	+
4F	Sucrose	SUC	+
2F	Mannitol	MNT	-
1F	Maltotriose	MTT	+
4G	Arabinose	ARA	-
2G	Glycerol	GLR	+
1G	Fructose	FRU	+
4H	p-n-p-β-D-glucoside	BGL	v
2H	p-n-p-β-D-cellobioside	PCE	-
1H	Proline & Leucine-p-nitroanilide	PLN	+
4I	p-n-p-phosphate	PHO	v
2I	p-n-p-α-D-maltoside	PAM	-*
1I	ONPG & p-n-p-α D-galactoside	PGO	-
4J	Urea	URE	-
2J	Esculin	ESC	-
1J	Arginine	ARG	v

* = variable when tested from Columbia Blood Agar

Table 5
Additional Quality Control Strains for BBL Crystal™ GP ID System
After 18–20 Hours Incubation from TSA II or Columbia Blood Agar

Panel Location	Substrate	Code	*Staphylococcus epidermidis* ATCC 12228	*Bacillus brevis* ATCC 8246	*Enterococcus faecalis* ATCC 19433	*Staphylococcus xylosus* ATCC 35033
4A	Fluorescent negative control	FCT	-	-	-	-
2A	4MU-β-D-glucoside	FGC	-	+	+	-
1A	L-valine-AMC	FVA	-	v	-	-
4B	L-phenylalanine-AMC	FPH	-	+	+	-
2B	4MU-α-D-glucoside	FGS	-*	+	+	-
1B	L-pyroglutamic acid-AMC	FPY	-	+	+	v
4C	L-tryptophan-AMC	FTR	-	+	+	v
2C	L-arginine-AMC	FAR	v	+	-	-
1C	4MU-N-acetyl-β-D-glucosaminide	FGA	-	+	+	-
4D	4MU-phosphate	FHO	+	v	v	+
2D	4MU-β-D-glucuronide	FGN	-	-	-	+
1D	L-isoleucine-AMC	FIS	-	v	-	-
4E	Trehalose	TRE	-	-	+	+
2E	Lactose	LAC	+	-	+	+
1E	Methyl-α & β-glucoside	MAB	-	-	+	+
4F	Sucrose	SUC	+	-	+	+
2F	Mannitol	MNT	-	-	+	+
1F	Maltotriose	MTT	+	-	+	-*
4G	Arabinose	ARA	-	-	-	v
2G	Glycerol	GLR	+	-	+	+
1G	Fructose	FRU	+	-	+	+
4H	p-n-p-β-D-glucoside	BGL	-	v	+	+
2H	p-n-p-β-D-cellobioside	PCE	-	-	+	-
1H	Proline & Leucine-p-nitroanilide	PLN	v	v	-	-
4I	p-n-p-phosphate	PHO	v	v	v	+
2I	p-n-p-α-D-maltoside	PAM	-*	v	+	-*
1I	ONPG & p-n-p-α–D-galactoside	PGO	v	-	-	v
4J	Urea	URE	+	v	v	+
2J	Esculin	ESC	-	v	+	-
1J	Arginine	ARG	v	+	+	v

* = variable when tested from Columbia Blood Agar

Table 6

Expected Reactions for Species Most Frequently Encountered in BBL Crystal™ GP ID System Clinical Trials

Organism	FCT	FGC	FVA	FPH	FGS	FPY	FTR	FAR	FGA	FHO	FGN	FIS	TRE	LAC	MAB	SUC	MNT	MTT	ARA	GLR	FRU	BGL	PCE	PLN	PHO	PAM	PGO	URE	ESC	ARO
E. faecalis	–	+	–	+	+	+	+	–	+	–	–	–	+	V	+	(+)	+	+	V	+	+	+	+	–	V	+	–	(–)	+	+
E. faecium	–	+	–	+	(–)	+	+	–	+	–	–	–	+	+	V	(+)	+	+	+	V	+	+	+	–	(–)	+	(+)	–	+	+
S. aureus	–	–	–	–	–	(–)	V	+	–	+	–	–	(+)	V	(+)	+	+	+	–	+	+	(+)	–	–	+	V	–	–	–	(+)
S. capitis	–	–	–	–	–	–	–	V	–	(–)	–	–	–	–	–	–	V	–	–	+	(+)	–	–	–	V	–	–	–	–	(+)
S. epidermidis	–	–	–	–	–	–	–	(–)	–	+	–	–	–	+	–	+	–	+	–	+	+	(–)	–	V	(+)	V	(–)	+	–	V
S. haemolyticus	–	–	–	–	–	+	–	(–)	V	–	(–)	–	(+)	V	(–)	+	V	+	–	+	(+)	V	–	–	V	V	(–)	–	–	V
S. hominis	–	–	–	–	–	–	–	V	–	–	–	–	V	V	–	V	–	(+)	–	+	+	(–)	–	V	V	V	(–)	+	–	–
S. agalactiae	–	–	V	+	(+)	–	+	+	–	+	V	V	+	V	+	+	V	+	–	V	+	(+)	–	V	+	–	(–)	–	–	V
S. bovis	–	+	+	+	+	–	+	V	V	–	V	+	(+)	+	+	+	V	+	–	–	+	+	+	(+)	V	–	+	–	+	–
S. pneumoniae	–	V	+	+	+	–	+	+	+	–	–	+	–	–	–	–	–	–	–	–	–	V	V	(+)	–	V	+	–	–	(–)
S. pyogenes	–	–	+	+	V	+	+	+	–	+	(–)	+	+	+	+	+	–	+	–	(+)	+	V	–	(+)	+	(–)	–	–	V	V

KEY: + = 90% positive; (+) = 75–89% positive; V = 26–74% positive; (–) = 11–25% positive; – = 10% positive.

Table 7

Accuracy of Identification for Species Most Frequently Encountered in BBL Crystal™ GP ID System Clinical Trial

Organism	Number Tested	BBL Crystal Correct ID	BBL Crystal Correct W/Supplemental Tests	Total Correct
Corynebacterium species	29	29	0	29
Enterococcus cassaliflavus/gallinarum	14	0	14[1]	14
Enterococcus faecalis	78	78	0	78
Enterococcus faecium	33	30	3	33
Micrococcus species	10	10	0	10
Staphylococcus aureus	88	85	3	88
Staphylococcus capitis	13	13	0	13
Staphylococcus epidermidis	87	87	0	87
Staphylococcus haemolyticus	23	23	0	23
Staphylococcus hominis	17	10	1	11
Streptococcus agalactiae	54	49	2	51
Streptococcus bovis	10	8	1	9
Streptococcus mitteri group	20	18	2	20
Streptococcus mitis group[2]	23	8	1	9
Streptococcus pneumoniae	54	45	8	53
Streptococcus pyogenes	50	49	0	49
Other *	132	81	10	91
Grand Total	735	623	45	668

Key: * = This category comprises all isolates where less than 10 were encountered in clinical trials.
1 = Colony pigmentation is the sole supplemental test required to obtain correct identification.
2 = As follow-up to this group's accuracy results, remedial actions were subsequently implemented to improve performance.

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ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden)

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