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Helping all people
 live healthy lives

August, 2015

Dear Valued BD Customer:

This letter is to inform you that BD is amending the BBL™ Media Package Inserts (PIs) for CLSI-exempt media in view of the upcoming IQCP requirements. The PIs will be updated to include a statement indicating that each lot of media has been tested using appropriate quality control organisms and that this testing meets product specifications and CLSI standards, where relevant. As always, QC testing should be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory's standard quality control procedures. Each laboratory is solely responsible for the development of its own IQCP.

Please be advised that this letter supersedes the currently published PIs that recommend QC for BD-manufactured CLSI-exempt BBL™ media.

This letter has been submitted to Centers for Medicare and Medicaid Services (CMS).¹

The CLSI-exempt plated media include:

Cat. No.	Product Description	Plates/Pack
221836	BBL™ Bacteroides Bile Esculin Agar (BBE)	10
221808	BBL™ BCYE Agar*	10
221838	BBL™ Bile Esculin Agar	10
221841	BBL™ Brain Heart Infusion Agar with 10% Sheep Blood, Gentamicin and Chloramphenicol (Deep Fill)	20
297848	BBL™ Brucella Agar with 5% Sheep Blood, Hemin and Vitamin K1	20
297716	BBL™ Brucella Agar with 5% Sheep Blood, Hemin and Vitamin K1	100
297840	BBL™ Brucella Laked Blood Agar with Kanamycin and Vancomycin (KV),	20
221733	BBL™ CDC Anaerobe 5% Sheep Blood Agar	20
221734	BBL™ CDC Anaerobe 5% Sheep Blood Agar	100
221735	BBL™ CDC Anaerobe 5% Sheep Blood Agar with Kanamycin and Vancomycin (KV)*	20
221736	BBL™ CDC Anaerobe 5% Sheep Blood Agar with Kanamycin and Vancomycin (KV)*	10
221846	BBL™ CDC Anaerobe Laked Sheep Blood Agar with Kanamycin and Vancomycin (KV)*	20
221169	BBL™ Chocolate II Agar (GC II Agar with Hemoglobin and IsoVitaleX™)*	20

Cat. No.	Product Description	Plates/Pack
221267	BBL™ Chocolate II Agar (GC II Agar with Hemoglobin and IsoVitaleX™)*	100
221848	BBL™ CIN Agar	10
299579	BBL™ CIN Agar	100
221165	BBL™ Columbia Agar with 5% Sheep Blood	20
221263	BBL™ Columbia Agar with 5% Sheep Blood	100
221352	BBL™ Columbia CNA Agar with 5% Sheep Blood	20
221353	BBL™ Columbia CNA Agar with 5% Sheep Blood	100
297873	BBL™ Egg Yolk Agar, Modified	10
221355	BBL™ EMB Agar, Modified, Holt-Harris and Teague	100
221492	BBL™ Enterococcosel™ Agar	20
221493	BBL™ Enterococcosel™ Agar	100
297715	BBL™ GC-Lect™ Agar*	20
297928	BBL™ GC-Lect™ Agar*	100
221365	BBL™ Hektoen Enteric Agar	20
221366	BBL™ Hektoen Enteric Agar	100
297799	BBL™ Inhibitory Mold Agar (Deep Fill)	10
298191	BBL™ Inhibitory Mold Agar (Deep Fill)	100
297800	BBL™ Inhibitory Mold Agar with Gentamicin (Deep Fill)	10
299715	BBL™ Inhibitory Mold Agar with Chloramphenicol and Gentamicin (Deep Fill)	10
221170	BBL™ Levine EMB Agar	20
221268	BBL™ Levine EMB Agar	100
221172	BBL™ MacConkey II Agar	20
221270	BBL™ MacConkey II Agar	100
221173	BBL™ Mannitol Salt Agar	20
221271	BBL™ Mannitol Salt Agar	100
221567	BBL™ Thayer Martin, Modified (MTM II) Agar*	20
221568	BBL™ Thayer Martin, Modified (MTM II) Agar*	100
221847	BBL™ Mycosel™ Agar (Deep Fill)	20
297755	BBL™ BC [Burkholderia (Pseudomonas) cepacia] Agar*	20
221179	BBL™ Phenylethyl Alcohol Agar with 5% Sheep Blood	20
221277	BBL™ Phenylethyl Alcohol Agar with 5% Sheep Blood	100
296272	BBL™ Potato Dextrose Agar	20
221180	BBL™ Sabouraud Dextrose Agar	20
221278	BBL™ Sabouraud Dextrose Agar	100
221849	BBL™ Sabouraud Dextrose Agar, Emmons	20
221867	BBL™ Sabouraud Dextrose Agar, Emmons	100
296359	BBL™ Sabouraud Dextrose Agar with Chloramphenicol and Gentamicin (Deep Fill)	20
221181	BBL™ Salmonella Shigella Agar	20
221279	BBL™ Salmonella Shigella Agar	100

Cat. No.	Product Description	Plates/Pack
221539	BBL™ Schaedler Agar with Vitamin K ₁ and 5% Sheep Blood	20
221934	BBL™ Selective Streptococcus Agar	20
221935	BBL™ Selective Streptococcus Agar	100
221809	BBL™ SXT Blood Agar	20
221810	BBL™ SXT Blood Agar	100
221872	BBL™ TCBS Agar	10
221239	BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II)	20
221261	BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II)	100
221162	BBL™ Trypticase™ Soy Agar with 10% Sheep Blood	20
221192	BBL™ XLD Agar	20
221284	BBL™ XLD Agar	100

CLSI-exempt tubed media include:

Cat. No.	Product Description	Ea/Pack
221409	BBL™ Bile Esculin Agar Slants	10
221410	BBL™ Bile Esculin Agar Slants	100
220830	BBL™ Blood Agar Slants	10
220831	BBL™ Blood Agar Slants	100
221610	BBL™ Brain Heart Infusion Agar Slants	10
221195	BBL™ Fluid Thioglycollate Medium, 8 mL	10
221196	BBL™ Fluid Thioglycollate Medium, 8 mL	100
220889	BBL™ Fluid Thioglycollate Medium, 20 mL	100
299803	BBL™ Fluid Thioglycollate Medium, 20 mL	100
221729	BBL™ GN Broth, 8 mL	10
221730	BBL™ GN Broth, 8 mL	100
292209	BBL™ Lim Broth, 5 mL	10
296266	BBL™ Lim Broth, 5 mL	100
221116	BBL™ Lowenstein-Jensen Medium Mycoflask™	100
220908	BBL™ Lowenstein-Jensen Medium Slants	10
220909	BBL™ Lowenstein-Jensen Medium Slants	100
221832	BBL™ Middlebrook 7H9 Broth with Glycerol	10
221414	BBL™ Mycobactosel™ L-J Medium Slants	100
220966	BBL™ Mycosel™ Agar Slants	10
220967	BBL™ Mycosel™ Agar Slants	100
221130	BBL™ Mycosel™ Agar, Mycoflask™ Bottles	10
221012	BBL™ Sabouraud Dextrose Agar Slants	10
221013	BBL™ Sabouraud Dextrose Agar Slants	100
296182	BBL™ Sabouraud Dextrose Agar Deep (Pour Tubes)	100
221136	BBL™ Sabouraud Dextrose Agar, Mycoflask™ Bottles	10

Cat. No.	Product Description	Plates/Pack
296308	BBL™ Sabouraud Dextrose Agar, Emmons, Pkg. of 10 Mycoflask™ bottles	10
221827	BBL™ Sabouraud Dextrose Agar, Emmons, Slants	100
221020	BBL™ Selenite-F Broth, 8 mL	10
221021	BBL™ Selenite-F Broth, 8 mL	100
221026	BBL™ Simmons Citrate Agar Slants	10
221742	BBL™ Thioglycollate Medium, Enriched with Vitamin K1, and Hemin, 5 mL	100
221787	BBL™ Thioglycollate Medium, Enriched with Vitamin K1, and Hemin, 8 mL	10
221788	BBL™ Thioglycollate Medium, Enriched with Vitamin K1, and Hemin, 8 mL	100
297292	BBL™ Thioglycollate Medium, Enriched with Vitamin K1, and Hemin, 10 mL	100
221199	BBL™ Thioglycollate Medium without Indicator-135C, 8 mL	10
221200	BBL™ Thioglycollate Medium without Indicator-135C, 8 mL	100
221047	BBL™ Thioglycollate Medium without Indicator-135C, 20 mL	100
295634	BBL™ Trypticase™ Soy Broth, 1 mL	100
221815	BBL™ Trypticase™ Soy Broth, 2 mL	100
221715	BBL™ Trypticase™ Soy Broth, 5 mL	10
221716	BBL™ Trypticase™ Soy Broth, 5 mL	100
221092	BBL™ Trypticase™ Soy Broth, 8 mL	10
221093	BBL™ Trypticase™ Soy Broth, 8 mL	100
297354	BBL™ Trypticase™ Soy Broth, 10 mL	100
221823	BBL™ Trypticase™ Soy Broth, 15 mL	100
221351	BBL™ Trypticase™ Soy Broth with 6.5% Sodium Chloride	100
221038	BBL™ TSI Agar Slants	10
221039	BBL™ TSI Agar Slants	100
221096	BBL™ Urea Agar Slants, Complete	10
221097	BBL™ Urea Agar Slants, Complete	100

Please contact Technical Services at 1-800-638-8663 with any questions. Thank you for your continued support of BD media.

Best regards,



Dan Bistimovich
U.S. Marketing, Clinical Microbiology

* Quality control testing of exempt media is strongly recommended by CLSI M22-A3 when using specialty media for recovery of fastidious organisms or anaerobes.

1. Note that CMS is not in the position to approve or disapprove of the content of this letter. It was submitted to them for information purposes only.

Cust Ltr – IQCP Media Ltr (FINAL 7-24-15)

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