



Attention: Laboratory Manager

August, 2015

RE: Individual Quality Control Plan (IQCP) and Hardy Diagnostics manufactured CLSI M22 exempt media

Dear Valued Customer,

You may already be aware effective January 1, 2016 clinical laboratories will have only two options when performing quality control procedures. Beginning on this date, labs may choose to follow CMS/CLIA default quality control procedures or they may choose to develop an Individual Quality Control Plan (IQCP).

As a result of this change, Hardy Diagnostics is in the process of amending our clinical media technical documents, Instructions for Use (IFU), and Package Inserts (PI) concerning the quality control recommendations for CLSI exempt media in preparation for the upcoming IQCP requirements. Our documents will be updated to include a statement indicating each lot of commercially manufactured media has been tested using appropriate quality control organisms and specifications in accordance with CLSI standards, where applicable.

At this time, end users should continue to perform QC testing in accordance with applicable local, state, federal, or country regulations, accreditation requirements, and/or per laboratory standard quality control procedures. In addition, each laboratory is solely responsible for performing a risk assessment for the development of its own IQCP, and for monitoring the efficacy of the quality control plan through continuous quality assessment.

Until our documents have been fully reviewed and updated to conform to the 2016 guidelines, if needed, please note this letter supersedes the currently published technical documents, Instructions for Use (IFU), Package Insert (PI), and quality control recommendations for Hardy Diagnostics commercially manufactured CLSI exempt media.

Hardy Diagnostics CLSI exempt media include:

Cat. no.	Description	Pack
A90	Anaerobic PEA, HDx, 15x100mm plate	PK10
AG901	Anaerobic PEA, HDx, 15x100mm plate	PK1
G05	BBE Agar, HDx, 15x100mm plate	PK10
AG051	BBE Agar, HDx, 15x100mm plate	PK1
J102	BBE/LKV Biplate, HDx, 15x100mm biplate	PK10
AG061	BBE/LKV, HDx, 15x100mm biplate	PK1
G09	BCSA, for B. cepacia, HDx, 15x100mm plate	PK10
J66	BEA w/Azide CAN, HDx, 15x100mm biplate	PK10
L36	BHI Agar Slant, HDx, 16x100mm tube	PK20
L35	BHI Agar Slant, HDx, 20x125mm tube	PK20
W65	BHI Agar w/Bld, Chr&Gent, HDx, 15x100mm plate	PK10
X14	BHI Agar w/Bld, Chr&Gent, HDx, plstc HardyFlask	PK20
L31	BHI Agar w/Blood Slant, HDx, 20x125mm tube	PK20
A20	BHI Agar w/Blood, HDx, 15x100mm plate	PK10
X13	BHI Agar w/Blood, HDx, plstc HardyFlask	PK20

W15	BHI Agar, deep fill, HDx, 15x100mm plate	PK10
X10	BHI Agar, HDx, plstc HardyFlask	PK20
R10	BHI Broth, 0.5ml, HDx, 13x100mm tube	PK20
K25	BHI Broth, 10ml, HDx, 16x125mm tube	PK20
K110	BHI Broth, 1ml, HDx, 16x100mm tube	PK20
R15	BHI Broth, 2ml, HDx, 13x100mm tube	PK20
R20	BHI Broth, 5ml, HDx, 13x100mm tube	PK20
K27	BHI Broth, 5ml, HDx, 16x100mm tube	PK20
W185BX	BHIA w/ 5% SB, 37ml, HDx,25x100mm plate	PK50
G12	Bile Esculin Agar, BEA, HDx, 15x100mm plate	PK10
L10	Bile Esculin Agar, Slant, HDx,16x100mm tube	PK20
G11	Bile Esculin Azide Agar, HDx, 15x100mm plate	PK10
K11	Bile Esculin Azide Broth, HDx, 16x100mm tube	PK20
A10BX	Blood Agar 5%, HDx,15x100mm plate	PK100
J162	Blood Agar 5%/Mann.Salt, HDx, 15x100mm biplate	PK10
A71	Blood Agar, 10%, HDx, 15x100mm plate	PK10
A127	Blood Agar, 5%, 30ml, HDx, Nalgene Omniplate	PK10
A10	Blood Agar, 5%, HDx, 15x100mm plate	PK10
H28	Blood Agar, 5%, HDx, 15x150mm plate	PK10
L12	Blood Agar, 5%, Slant, HDx, 16x100mm tube	PK20
J22	Blood Agar, 5%/EMB Agar, HDx, 15x100mm biplate	PK10
J32BX	Blood Agar, 5%/MacConkey, HDx,15x100 biplate	PK100
A03	Blood Agar, EH, HDx, 15x100mm plate	PK10
A17BX	Blood Agar. 8%, HDx,15x100mm plate	PK100
J32	Blood, 5%/MacConkey, HDx,15x100mm biplate	PK10
J93	Blood/Blood Agar, 5%, HDx, 15x100mm biplate	PK10
A30	Brucella Agar w/H&K, HDx, 15x100mm plate	PK10
AG301	Brucella Agar w/H&K, HDx, 15x100mm plate	PK1
AG304	Brucella Agar w/H&K, HDx, 15x100mm plate	PK4
H05	Brucella Agar w/H&K, HDx, 15x150mm plate	PK10
W23	Brucella w/H&K, 26ml, HDx, 15x100mm plate	PK10
J74	Brucella/Anaerobic PEA, HDx, 15x100mm biplate	PK10
J87	Brucella/LKV Biplate, HDx, 15x100mm biplate	PK10
G20	CIN Agar (Yersinia), HDx, 15x100mm plate	PK10
J52	CNA Agar/EMB Agar, HDx, 15x100mm biplate	PK10
J62BX	CNA Agar/MacConkey, HDx,15x100 biplate	PK100
J62	CNA/MacConkey Agar, HDx,15x100mm biplate	PK10
A16	Columbia Blood Agar, HDx, 15x100mm plate	PK10
A50	Columbia CNA Agar, HDx, 15x100mm plate	PK10

A129	Columbia CNA Agar, HDx, Nalgene Omniplate	PK10
AG302	DuoPak A, HDx, 15x100mm plate	PK2
AG312	DuoPak B, HDx, 15x100mm plate	PK2
G215	Egg Yolk Agar, Mod., HDx, 15x100mm plate,	PK10
AG401	Egg Yolk Agar, Modified, HDx, 15x100mm plate	PK1
G263	EMB Agar (HHT), HDx, 15x100mm plate	PK10
G25	EMB Levine Agar, HDx, 15x100mm plate	PK10
K01	GN Broth, HDx, 16x100mm tube	PK20
K39	GN Broth,10ml, HDx, 16x125mm tube	PK20
GA72	Group A Beta Str, HDx,15x100mm plate	PK10
A72	Group A Beta Strep Agar, HDx, 15x100mm plate	PK10
J92	Grp A Beta Strep/Blood,5%, HDx, 15x100mm biplate	PK10
G63	HE Agar, HDx, 15x100mm plate	PK10
J415	HE Agar, HDx, 15x100mm quadplate	PK10
J139	HE Agar/SS Agar, HDx, 15x100mm biplate	PK10
A112	Heart Infusion Agar w/SB, HDx, 15x100mm plate	PK10
A149	Horse Blood Agar 5%, HDx, 15x100mm plate	PK10
L47	Inhib.Mold Agar Slant, HDx, 20x125mm tube	PK20
W27	Inhib.Mold Agar w/Genta, HDx, 15x100mm plate	PK10
W25	Inhib.Mold Agar, HDx, 15x100mm plate	PK10
L49	Inhibitory Mold Ag w/Gent, HDx,20x125 tube slant	PK20
X20	Inhibitory Mold Agar, HDx, plstc HardyFlask	PK20
L57	LIM Broth for GrpB Strep, HDx, 16x100mm tube	PK20
C27	LJ Deep, HDx, 20x150mm tube	PK20
X22	LJ Media Slant, HDx, plstc HardyFlask	PK20
C21	LJ Slant, HDx, 20x125mm tube	PK20
C29	LJ w/NaCl Slant, HDx, 20x125mm tube	PK20
C28	LJ w/Pyruvate Slant, HDx, 20x125mm tube	PK20
X19	LJ w/Pyruvate, HDx, plstc HardyFlask	PK20
A60	LKV Agar, HDx, 15x100mm plate	PK10
AG601	LKV Agar, HDx, 15x100mm plate	PK1
X21	Lowenstein Jensen w/Iron, HDx, plstc HardyFlask	PK20
Q63	MacConkey Agar Deep, HDx, 20x150mm tube	PK20
L30	MacConkey Agar Slant, HDx, 16x100mm tube	PK20
G35	MacConkey Agar, HDx, 15x100mm plate	PK10
G35BX	MacConkey Agar, HDx,15x100mm plate	PK100
J58	MacConkey/EMB Agar, HDx, 15x100mm biplate	PK10
J118	MacConkey/MacConkey Agar, HDx, 15x100mm biplate,	PK10
G40	Mannitol Salt Agar, HDx, 15x100mm plate	PK10

C32	Middlebrook 7H9 Broth, HDx, 16x125mm tube	PK20
U32	Middlebrook 7H9 Broth, HDx, 500ml Bottle	PK1
C62	Middlebrook 7H9 Brth w/Tw, HDx, 16x125mm tube	PK20
AG303	MultiPak A, HDx, 15x100mm plate	PK3
AG313	MultiPak B, HDx, 15x100mm plate	PK3
L45	Mycobiotic Agar Slant, HDx, 20x125mm tube	PK20
W50	Mycobiotic Agar, HDx, 15x100mm plate	PK10
X30	Mycobiotic Agar, HDx, plstc HardyFlask	PK20
Q84	Nutrient Agar, HDx, 20x150mm tube	P100
R154	Rapid Urea Medium, HDx, 13x100mm tube	PK20
A66	Rose Agar (CNA+PEA), HDx, 15x100mm plate	PK10
J88	Rose/EMB Agar, HDx, 15x100mm biplate	PK10
J85	Rose/MacConkey Agar, HDx, 15x100mm biplate	PK10
L40	Sabdex Agar Slant, HDx, 20x125mm tube	PK20
W72	Sabdex Agar w/Chloram., HDx, 15x100mm plate	PK10
X41	Sabdex Agar w/Chloram., HDx, plstc HardyFlask	PK20
W250	SabDex Agar, 60ml, HDx, 25x100mm plate	PK5
U356	SabDex Agar, Emmons 400ml, HDx, 500ml PC bottle	PK10
W20	Sabdex Agar, Emmons, HDx, 15x100mm plate	PK10
X57	Sabdex Agar, Emmons, HDx, plstc HardyFlask	PK20
W70	Sabdex Agar, HDx, 15x100mm plate	PK10
X40	Sabdex Agar, 12 ml, HDx, plstc HardyFlask	PK20
Q34	SabDex Agr w/Chloram 18mL, HDx, 20x125mm tube	PK20
K54	Sabdex Broth, HDx, 16x125mm tube	PK20
W73	Sabdex C&G, HDx, 15x100mm plate	PK10
W75	SabHI Agar, HDx, 15x100mm plate	PK10
X75	SabHI Agar, HDx, plstc HardyFlask	PK20
K69	Selenite Cystine Broth, HDx, 16x125mm tube	PK20
K45	SF Broth, HDx, 16x125mm tube	PK20
G50	SS Agar, HDx, 15x100mm plate	PK10
G55	TCBS Agar, for Vibrio, HDx, 15x100mm plate	PK10
K234	Thio w/H & K, 8ml, HDx, 16x100mm tube	PK20
K24	Thio w/H&K, 10ml, HDx, 16x125mm tube	PK20
K22	Thio w/H&K, 5ml, HDx, 16x100mm glass tube	PK20
AG23H	Thio w/H&K, 7ml, HDx, 16x125mm tube	PK20
AG22H	Thio w/H&K, 9ml, HDx, 16x125mm tube	PK20
K21	Thio w/Indicator, 10ml, HDx, 16x125mm tube	PK20
K29	Thio w/o Indicator, 10ml, HDx, 16x125mm tube	PK20
K28	Thio w/Supplements, 15ml, HDx, 20x125mm tube	PK20

K23	Thio w/Supplements, HDx, 16x125mm tube	PK20
L60	TSA Slant, HDx, 16x100mm tube	PK20
G60	TSA, HDx, 15x100mm plate	PK10
G60BX	TSA, HDx, 15x100mm plate	PK100
J160	TSA/Blood Agar 5%, HDx, 15x100mm biplate	PK10
J108	TSA/TSA, HDx, 15x100mm biplate	PK10
R36	TSB, 1ml, HDx, 13x100mm tube	PK20
R31	TSB, 2ml, HDx, 13x100mm tube	PK20
K131	TSB, 2ml, HDx, 16x100mm tube	PK20
R41	TSB, 3ml, HDx, 13x100mm tube	PK20
R30	TSB, 5ml, HDx, 13x100mm tube	PK20
K89	TSB, 5ml, HDx, 16x100mm tube	PK20
K88	TSB, 9ml, HDx, 16x100mm tube	PK20
K285	TSB, Filt 2mL, HDx, 16x100mm tube	PK20
K85	TSB, Filtered, 1ml, HDx, 16x100mm tube	PK20
L16	TSI Agar Slant, 6ml, HDx, 16x100mm tube	PK20
R32	TSI Agar Slant, HDx, 13x100mm tube	PK20
L50	TSI Agar Slant, HDx, 16x125mm tube	PK20
S15	TSI Agar Slit, SlipCap, 10ml, HDx, 16x125 Round Bottom tube	P100
R42	Urea Agar Slant, HDx, 13x100mm tube	PK20
L65	Urea Agar Slant, HDx, 16x100mm tube	PK20
Y141	Urea R Broth, 1ml, HDx, 13x100mm tube	PK20
G65	XLD Agar, HDx, 15x100mm plate	PK10

Please contact our Technical Services Department at 800.266.2222, option 2 or via email at TechService@HardyDiagnostics.com if you have any questions or concerns. Thank you for your continued support and for choosing Hardy Diagnostics as your media supplier.

Kind regards,



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