510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

Submitter´s Details

Name:	Bio-Rad Medical Diagnostics GmbH
Address:	Industriestrasse 1, 63303 Dreieich, Germany
Telephone number:	+49 (0) 6103 3130-442
Fax number:	+49 (0) 6103 3130-646
Establishment Registration Number:	9610824
Contact Person:	Dr. Rolf Vornhagen
Date of Summary:	December 12, 2017

Name of Device

Trade Name:	IH-Internal QC
Classification Name:	Kit, Quality Control For Blood Banking Reagents
510(k) number:	BK170064
Device Class:	II
Product Code:	KSF
Regulation number:	21 CFR 864.9650

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	DG Gel Extended Control
Classification Name:	Kit, Quality Control For Blood Banking Reagents
510(k) number:	BK140092
Device Class:	II
Product Code:	KSF
Regulation number:	21 CFR 864.9650
Clearance Letter:	April 11, 2014

Description of the Device

IH-Internal QC is intended as QC for IH-Reagents, including Blood Grouping Reagents (BGRs), Reagent Red Blood Cells (RRBCs) and the Anti-IgG component of Anti-Human Globulin (AHG) to ensure their accuracy and the blood grouping serological results' safety.

IH-Internal QC consists of human red blood cells suspensions and Group O or AB serum samples with and without diluted polyclonal antibodies as described below. The serum samples are ready-to-use. The reagents are preserved with 2.5 mg/L (0.01 mM) Trimethoprim and 47.5 mg/L (0.19 mM) Sulfamethoxazol.

Each packaging of IH-Internal QC contains the following profile:

IH-Internal QC Sample 1	AB, RhD positive
IH-Internal QC Sample 2	O, RhD negative ccee
IH-Internal QC Sample 3	O, RhD positive, CcEe, K positive
IH-Internal QC Sample 4	O, RhD weak
IH-Internal QC Sample 5	DAT positive
IH-Internal QC Serum 1	Group AB serum and diluted polyclonal Anti-Fya
IH-Internal QC Serum 2	Group O serum and diluted polyclonal Anti-E
IH-Internal QC Serum 3	Group O serum

Intended Use

The IH-Internal QC is intended for blood grouping controls including antisera for ABO/Rh, Rh Phenotyping, K, Reagent Red Blood Cells and reagents for antibody detection and identification The IH-Internal QC is designed to be used with IH-Cards only with the manual method.

The IH-Internal QC is "Rx only"

List of Reagents to be used with the Subject Device

IH-Reagents to be used with IH-Internal QC and being applicable to a Biologics License Application (BLA) are listed below.

BLA	Product Name	STN BL
Blood Grouping Reagent	IH-Card ABO/D(DVI-)+RevA1,B	125094*, 125532
	IH-Card ABO/D(DVI+)+RevA1,B	125094*, 125532
	IH-Card ABO/RhD(DVI+)	125094*, 125529, 125532
	IH-Card Group A,B	125094*
	IH-Card Group ABO	125094*, 125532
	IH-Card ABD(DVI-)-Conf	125094*, 125532
	IH-Card ABD(DVI+)-Conf	125094*, 125532
	IH-Card Rh-Phenotype+K	125094*
	IH-Card Anti-C	125094*
	IH-Card Anti-E	125094*
	IH-Card Anti-c	125094*
	IH-Card Anti-e	125094*
	IH-Card Anti-D (DVI+)	125094*
	IH-Card Anti-D (DVI-)	125094*
	IH-Card Anti C-E-K	125094*
	IH-Card Anti-K	125094*
	IH-Card RhD(DVI-) +Phenotype	125094*
	IH-Anti-D Blend	125533
Anti-Human Globulin	IH-Card AHG Anti-IgG,-C3d	125529
	IH-Card AHG Anti-IgG	125098
Reagent Red Blood Cells	IH-Cell I-II	125208
	IH-Cell I-II-III	
	IH-Cell Pool	
	IH-Panel 11	
	IH-Panel 11 Papain	
	IH-Panel Plus 6	

* Trans-BLA STN BL 125094

Device Comparison

The table below provides a comparison between IH-Internal QC and its predicate device DG Gel Extended Control (BK140092). The devices are compared based on indications for use and material.

Parameter	**Predicate Device** **Medion Grifols Diagnostics AG** **DG Gel Extended Control**	**Subject Device** **Bio-Rad Laboratories** **IH-Internal QC**
Indications for Use	DG Gel Extended is intended to allow regular quality control of materials, work procedures and instruments procedures for: Determination of ABO, Rh, K antigens Determination of the appropriate ABO blood group antibodies Detection of unexpected antibodies ABO compatibility. For use with the DG Gel 8 technique.	The IH-Internal QC is intended for blood grouping controls including antisera for ABO/Rh, Rh Phenotyping, K, Reagent Red Blood Cells and reagents for antibody detection and identification The IH-Internal QC is designed to be used with IH-Cards only with the manual method . The IH-Internal QC is "Rx only".
Classification	Class II Kit, Quality Control For Blood Banking Reagents 21 CFR 864.9650	Class II Kit, Quality Control For Blood Banking Reagents 21 CFR 864.9650
Product Code	KSF	KSF
Storage	2 to 8 °C	same
Tests performed	• Typing of ABO, RhD, Rh phenotyping and K antigens • Determination of ABO blood group antibodies • Detection of unexpected antibodies • Direct Antiglobulin Testing (DAT)	same
Techniques	**Manual Method:** For DG Gel 8 Technique	**Manual Method:** For the manual method using IH System (IH Gel Card Technique)
	Automated Method: For automated methods including WADiana® Compact and Eryta® analyzers using column agglutination with DG Gel 8 technique.	**Not applicable**
Reagent Preparation	Ready-to-use	Requires preparation of quality control samples
Hematocrit	15.0 ± 2 %	4.0 ± 1 %
No. of vials	4 vials;	8 vials;

	containing cells (Reference Blood Cells) and antibodies (Reactivity Testing Sera)	5 vials containing red blood cell suspensions and 3 vials with serum samples

Performance Testing

The correct performance of IH-Internal QC was confirmed by comparing the expected results with the results obtained during performance testing. All required performance tests with IH-Internal QC during the clinical testing at two external sites in the US have been conducted with acceptable results. The results confirm the satisfactory performance of the IH-Internal QC kit and its suitability as control reagents for manual methods using for IH Gel Card technique.

Based on all information submitted, Bio-Rad concludes that IH-Internal QC is substantially equivalent to the predicate device and has been demonstrated to be safe and effective to be marketed in the U.S.A.