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K960827

**BECTON  
DICKINSON**

**510(K) SUMMARY**

**SUBMITTED BY:** BECTON DICKINSON PRIMARY  
CARE DIAGNOSTICS  
BECTON DICKINSON AND COMPANY  
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SPARKS, MD 21152

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**PREPARED:** February 21, 1996

**TRADE NAME:** QBC® AUTOREAD™ System

**COMMON NAME:** Automated Differential Cell Counter

**CLASSIFICATION  
NAME:** Automated Differential Cell Counter

**PREDICATE DEVICE:** QBC® AUTOREAD™ System (K910834)  
QBC® AccuTube for QBC® AUTOREAD™ (K953340)

**INTENDED USE:** The QBC® AUTOREAD™ System provides a diagnostic hematology profile on venous or capillary blood: hematocrit, hemoglobin, MCHC, platelet count, white blood cell count, granulocyte count (% and number), and lymphocyte/monocyte count (% and number).

**DEVICE DESCRIPTION:** The QBC® AUTOREAD™ System includes an analyzer, power pack, printer, centrifuge, and test accessories. The system uses specially designed tubes known as the QBC® AccuTube. AccuTubes are filled with blood and centrifuged. The spun tube is placed in the QBC® AUTOREAD™ analyzer which provides a report.

**DEVICE TECHNOLOGICAL CHARACTERISTICS:**

Tables 1 summarizes the similarities to and differences from currently marketed and/or cleared devices.

**TABLE 1: SUMMARY OF SIMILARITIES TO AND DIFFERENCES FROM CURRENTLY MARKETED AND/OR CLEARED DEVICES**

PRODUCT ATTRIBUTES	PRODUCT NAME		
	QBC AUTOREAD System K910834	QBC AccuTube for AUTOREAD System K953340	QBC AUTOREAD System (as configured and presented in this submission)
<b>SYSTEM HARDWARE</b>	QBC AUTOREAD	QBC AUTOREAD	QBC AUTOREAD
<b>TUBE TYPES</b>	2 tube types: venous and capillary	1 tube type: QBC AccuTube [or] 2 tube types: venous and capillary	1 tube type: QBC AccuTube (modified) [or] 2 tube types: venous and capillary
<b>TUBE FILLING MECHANISM FOR VENOUS BLOOD SAMPLES</b>	QBC Pipetter	QBC Pipetter	QBC Pipetter [or] AccuTube filled via capillary action
<b>TUBE FILLING MECHANISM FOR CAPILLARY (FINGER STICK) BLOOD SAMPLES</b>	Capillary action	Capillary action	Capillary action
<b>SYSTEM HEMATOLOGY PARAMETERS</b>	White Blood Cell Granulocyte Lymph/Mono Platelet Hematocrit Hemoglobin MCHC	White Blood Cell Granulocyte Lymph/Mono Platelet Hematocrit Hemoglobin MCHC	White Blood Cell Granulocyte Lymph/Mono Platelet Hematocrit Hemoglobin MCHC
<b>FIBRINOGEN TESTING CAPABILITIES</b>	Available	Available	Available
<b>BAR CODE/POSITIVE PATIENT IDENTIFICATION</b>	Not available	Not available	Available for QBC AccuTube
<b>HEMATOLOGY DIAGNOSTICS REPORTS</b>	Available	Available	Available

**TABLE 1 (Continued): SUMMARY OF SIMILARITIES TO AND DIFFERENCES FROM CURRENTLY MARKETED AND/OR CLEARED DEVICES**

<b>PRODUCT ATTRIBUTES</b>	<b>PRODUCT NAME</b>		
	<b>QBC AUTOREAD System K910834</b>	<b>QBC AccuTube for AUTOREAD System K953340</b>	<b>QBC AUTOREAD System (as configured and presented in this submission)</b>
<b>OUT OF RANGE VALUES</b>	Values outside the validated operating range are shown blinking on the AUTOREAD display; values are flagged as out of range on the sample printout	Values outside the validated operating range are shown blinking on the AUTOREAD display; values are flagged as out of range on the sample printout	Values outside the validated operating range are shown blinking on the AUTOREAD display; values are flagged as out of range on the sample printout
<b>MODE FEATURES/SELECTION FOR CONTROL, PROFICIENCY TEST, CHECK ROD, AND PATIENT SPECIMEN TESTING</b>	Modes manually selected by operator  6 modes	Modes manually selected by operator  5 modes	Modes manually selected by operator  5 modes

**SUMMARY OF DEVICE TESTING:**

**ACCURACY STUDIES**

Accuracy data for the QBC AUTOREAD System is derived from K953340; performance of the QBC AUTOREAD System with the modified QBC AccuTube disposable is equivalent to that of the QBC AUTOREAD System with the original QBC AccuTube disposable. The hardware utilized by both systems to read the AccuTube is identical. The disposable is identical with the exception of movement of the reagent coating to facilitate filling of the AccuTube via capillary action and incorporation of a fluorescent stripe on the outside of the tube for positive tube type identification. Calculation algorithms are identical with the exception of adjustments made to the hematocrit and hemoglobin algorithms to compensate for movement of the reagent coating within the AccuTube.

A study was performed to demonstrate equivalency between the relocated reagent coating AccuTube/AUTOREAD System and the original AccuTube/AUTOREAD System in terms of hematocrit and hemoglobin values. The study was conducted at two hospital sites with a total of 160 fresh EDTA whole blood samples. Each sample was prepared in duplicate QBC AccuTubes with relocated reagent coating, duplicate QBC AccuTubes with original reagent coating location and duplicate microhematocrit tubes. A scatter plot comparing the relocated QBC AccuTube read with the modified QBC AUTOREAD algorithm and the spun microhematocrit method was performed. Regression statistics are summarized below:

<b>HEMATOCRIT STUDY</b>		
<b>CORRELATION COEFFICIENT</b>	<b>SLOPE</b>	<b>INTERCEPT</b>
0.993	0.991	0.270

An additional scatter plot comparing the relocated QBC AccuTube read with the modified QBC AUTOREAD algorithm and the original QBC AccuTube read with the original QBC AUTOREAD algorithm was performed. Regression statistics are summarized below:

<b>HEMATOCRIT STUDY</b>		
<b>CORRELATION COEFFICIENT</b>	<b>SLOPE</b>	<b>INTERCEPT</b>
0.999	0.975	1.015

This study demonstrates that QBC AccuTubes with relocated reagent coating read with a QBC AUTOREAD System provide equivalent results when compared to the spun microhematocrit method and to the original QBC AccuTube read with the original QBC AUTOREAD algorithm.

Impedance values for hemoglobin were collected from the hospitals and compared to QBC AccuTubes and non-relocated QBC AccuTubes. A scatter plot comparing the relocated QBC AccuTube read with the modified QBC AUTOREAD System data and the impedance system data was performed. Regression statistics are summarized below:

<b>HEMOGLOBIN STUDY</b>		
<b>CORRELATION COEFFICIENT</b>	<b>SLOPE</b>	<b>INTERCEPT</b>
0.995	0.969	0.410

An additional scatter plot comparing the relocated QBC AccuTube read with the modified QBC AUTOREAD algorithm and the original QBC AccuTube read with the original QBC AUTOREAD algorithm was performed. Regression statistics are summarized below:

<b>HEMOGLOBIN STUDY</b>		
<b>CORRELATION COEFFICIENT</b>	<b>SLOPE</b>	<b>INTERCEPT</b>
0.999	0.981	0.239

These studies demonstrate that QBC AccuTubes with relocated reagent coating read with a QBC AUTOREAD System provide equivalent results when compared to the impedance cell counter method and to the original QBC AccuTube read with the original QBC AUTOREAD algorithm.

Scatter plots were prepared for all other hematological parameters comparing the relocated QBC AccuTube read with the modified QBC AUTOREAD algorithm and the original QBC AccuTube read with the original QBC AUTOREAD algorithm. Regression statistics are summarized below:

<b>PARAMETER</b>	<b>CORRELATION COEFFICIENT</b>	<b>SLOPE</b>	<b>INTERCEPT</b>
<b>PLATELETS</b>	0.989	0.932	11.633
<b>WHITE BLOOD CELLS</b>	0.984	1.031	-0.116
<b>GRANULOCYTES (#)</b>	0.985	1.045	0.002
<b>LYMPHOCYTES/ MONOCYTES (#)</b>	0.967	0.921	0.080

## **PRECISION STUDY**

Accuracy data for the QBC AUTOREAD System is derived from K953340; performance of the QBC AUTOREAD System with the modified QBC AccuTube disposable is equivalent to that of the QBC AUTOREAD System with the original QBC AccuTube disposable.

## **CONCLUSION:**

Evaluation of the QBC® AUTOREAD™ System has demonstrated its equivalency to the predicate device in terms of accuracy and precision.