BECKMAN COULTER

Dated: 30/05/2023

CALIBRATION CERTIFICATE

Name of the customer	Cluepath Diagnostics
Make	Beckman Coulter
Product Name	DXH-520 – Hematology Analyzer
Serial No	BG010057

This is to certify that the DXH-520 Hematology Analyzer installed at the above-mentioned customer site has been calibrated with S-CAL calibrator (Lot no:492316300, Expiry: 30/05/2023)

S.No	Procedures	Parameter	Remarks
1	Startup Check	WBC/RBC/HGB/PLT	PASS
2	Reproducibility	WBC/RBC/HGB/MCV/RDW/PLT/MPV	PASS
3	Carryover	WBC/RBC/HGB/PLT	PASS
4	QC Trilevel	WBC/RBC/HGB/HCT/PLT	PASS
5	Calibration cal (Lot No: 492316300)	WBC/RBC/HGB/MCV/PLT/MPV	PASS

Date of Calibration : 30/05/2023	**Due date for Calibration: 29/05/2024**

For Beckman Coulter India Private Limited

Naveen Kumar BR,
Application Specialist,
Bangalore.

COULTER S-CAL Calibrator Kit

REF 628026 - 1 x 3.3 mL

PN A59927-AC

CE BECKMAN COULTER

For *In Vitro* Diagnostic Use

INTENDED USE
S-CAL Calibrator is intended for the determination of calibration factors for UniCel DxH Coulter Cellular Analysis Systems listed in the TABLE OF EXPECTED RESULTS, in conjunction with specific COULTER reagents. Refer to the Instructions for Use or System HELP.

SUMMARY AND PRINCIPLE
Coulter Cellular Analysis Systems, for which this kit was designed, require a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms.

The parameters (WBC, RBC, HGB, MCV, PLT and MPV) are calibrated using S-CAL Calibrator, a stabilized human-blood preparation. S-CAL Calibrator is an acceptable alternative to whole-blood calibration.

The calibration procedure uses replicate measurements of S-CAL Calibrator. The average result for each parameter is divided into the S-CAL Calibrator Assigned Value to give a calibration factor.

HCT, MCH, MCHC, RDW, NRBC, Retic and DIFF parameters do not require calibration.

REAGENTS
S-CAL Calibrator consists of treated, stabilized, human erythrocytes and platelet sized components in an isotonic medium. Fixed erythrocytes are added to simulate leukocytes.

WARNINGS
POTENTIAL BIOHAZARDOUS MATERIAL
Product contains biologically sourced materials: Human, Avian, Reptile and Ungulate.

Each human donor unit used in preparation of the material was tested by an FDA approved method for the presence of antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-2) and Hepatitis C Virus (HCV) as well as for Hepatitis B virus surface antigen and found to be negative (were not repeatedly reactive.)

Because no test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV-1 and HIV-2), or other infectious agents are absent, this specimen/reagent should be handled at Biosafety Level 2, as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1988.

Product contains <0.1% Sodium Azide. Sodium Azide preservative may form explosive compounds in metal drain lines. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).

STORAGE, STABILITY AND DISPOSAL
The S-CAL Calibrator kit is shipped in a thermally insulated container designed to keep it cool. When stored at 2-8°C, sealed/unopened tubes are stable until the expiration date shown on the TABLE OF EXPECTED RESULTS. When the tubes are opened, the product is stable for 1 hour.

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations.

INDICATIONS OF INSTABILITY OR DETERIORATION
Inability to obtain expected values in the absence of known instrument problems or gross hemolysis (darkly-colored supernatant) is indicative of product deterioration. However, a slight pink color to the supernatant is normal and should not be confused with deterioration of the product.

MATERIALS PROVIDED
- COULTER S-CAL Calibrator.
- Table of Expected Results.

MATERIALS REQUIRED, BUT NOT PROVIDED
- Sufficient COULTER reagents to complete calibration.
- Instructions for Use or System HELP.
- 6C Cell Control Kit.

INSTRUCTIONS FOR USE
NOTE: Keep S-CAL Calibrator in the refrigerator until ready to begin Section II of INSTRUCTIONS FOR USE.

1. Before calibrating the instrument, refer to the appropriate Instructions for Use or System HELP, then go on to Section II.
2. DO NOT PROCEED IF INSTRUMENT PERFORMANCE DOES NOT MEET SPECIFICATIONS. CALL BECKMAN COULTER CUSTOMER SERVICE OR CONTACT YOUR LOCAL BECKMAN COULTER REPRESENTATIVE.
3. Calibration errors can be caused by:
   - Inadequate mixing
   - Excessive handling
   - Exceeding time limits
   - Failure to analyze a sufficient number of samples

IMPORTANT: Perform the following procedures exactly as described. Complete the entire procedure within 1 hour.

4. Remove S-CAL calibrator kit from the refrigerator and warm at AMBIENT TEMPERATURE for 15 minutes.
5. While the calibrator is equilibrating to ambient temperature, prepare the analyzer as follows:
   a. Select Calibration Setup from CBC Calibration Screen in QA Menu.
   b. Scan 2D barcode from the ASSAY SHEET to upload the assigned values.
6. After warming the S-CAL Calibrator, mix by hand as follows:

   NOTE: Do **NOT** use a mechanical mixer.

   a. Roll the tube slowly between the palms of the hands eight times in an upright position.
   b. Invert the tube and slowly roll it between the palms eight times.
   c. Gently invert the tube eight times.

   d. Repeat steps 6a through 6c.
   e. Inspect the tube contents to determine if all cells have been uniformly distributed.
   f. Repeat the mixing procedure if tube contents have not been uniformly distributed.
7. Analyze S-CAL Calibrator 10 times in Cassette Presentation Mode, following Instructions for Use or System HELP.

CHECK CALIBRATION CRITERIA
The DxH systems check the following criteria automatically and flag the calibration results with a yellow background if you need to calibrate a parameter or with a red background if there may be a problem.

Check calibration results. Calibration is required if the Difference is greater than DIFFERENCE LOWER LIMIT MAX and the Factor % Diff is greater than the FACTOR % DIFFERENCE LOWER LIMIT MAX.

PARAMETER	CALIBRATE IF DIFFERENCE LOWER LIMIT MAX	CALIBRATE IF FACTOR % DIFF LOWER LIMIT MAX
WBC	>0.1	>1.25%
RBC	>0.03	>0.7%
Hgb	>0.1	>0.78%
MCV	>1.0	>1.18%
PLT	>6.0	>2.70%
MPV	>0.5	>5.0%

VERIFY CALIBRATION
1. Analyze 6C Cell Controls according to package insert instructions.
2. Your results for the cell control levels should be within the expected range as stated on the TABLE OF EXPECTED RESULTS in the 6C Cell Control kit.
3. If your cell control results are not within the expected range, repeat the sample. If the results of the second sample are not within the expected range, follow the Troubleshooting Procedure on the 6C Cell Control package insert and call Beckman Coulter Customer Service at 800-526-7694 (USA or Canada) or contact your local Beckman Coulter Representative.

ASSIGNED VALUES
The assigned values for WBC, RBC, HGB, MCV, PLT and MPV parameters are derived from sufficient samples to recover mean values with a high degree of statistical validity. Measurements are made on each of several COULTER instruments.

All instruments are traceable to whole-blood calibration and operated according to the appropriate Instructions for Use. Calibration stability is verified by comparison of instrument results and Reference Method results for fresh whole-blood specimens. System performance is monitored daily using 6C Cell Control at multiple levels.

Whole-blood calibration consists of K_3EDTA anticoagulated whole blood analyzed using the following reference methods:

WBC and RBC: A single-aperture impedance cell counter such as a COULTER Z Series cell counter and the manufacturer's recommended reagents. Macro dilutions are made using Class A glassware. Both WBC and RBC data are corrected for coincidence. The erythrocytes and leukocytes measurands (analytes) in this calibrator are traceable to Clin Lab Haemat, 1994, 16(2):131-138.

HGB: The hemoglobin measurand (analyte) in this calibrator is traceable to CLSI Standard H15-A3.[1] This hemiglobincyanide spectrophotometric procedure employs modified Drabkins (Ziljstra) Reagent and is referenced to NIST certified filters.

MCV: MCV is calculated: PCV/RBC x 10. Packed-cell volume (PCV) is measured by a hematocrit procedure according to CLSI Standard H7-A3.[2]

PLT: Phase contrast microscopy.

MPV: Latex particles (PN 7531820).

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the applicable Beckman Coulter reagent systems indicated in the calibrator Table of Expected Results (Assay Sheet).

Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

QUALITY CONTROL

After completing the calibration and verification procedures, the instrument is within the accuracy limit stated in your Product Manuals. Good laboratory practices recommend that each series of patient samples be preceded and followed by a quality-control check. Use COULTER cell controls to check the performance of the instrument

REFERENCES

1. Clinical and Laboratory Standards Institute. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood- Third Edition; Approved Standard. CLSI publication H15-A3. Wayne, PA, 2000.
2. Clinical and Laboratory Standards Institute. Procedure for Determining Packed Cell Volume by the Microhematocrit Method- Third Edition; Approved Standard. CLSI publication H7-A3. Wayne, PA, 2000.

PRODUCT AVAILABILITY

COULTER S-CAL Calibrator Kit
REF 628026 - 1 x 3.3 mL

TRADEMARKS

Beckman Coulter, the stylized logo, COULTER, DxH and UniCel are trademarks of Beckman Coulter, Inc. and are registered in the USPTO.

For additional information, or if damaged product is received, call Beckman Coulter Customer Service at 800-526-7694 (USA or Canada) or contact your local Beckman Coulter Representative.

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Brea, CA 92821 U.S.A.
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EC REP

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Mervue, Galway,
Ireland (353 91 774068)

Made in USA

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Revision History
Revision AC, 09/2012
Changes were made to:
- INTENDED USE

TECHNICAL MONOGRAPH

General Chemistry
Centrifugation
Disease Management
Immunodiagnostics
Clinical Research
Hematology
Hemostasis
Lab Automation
Data Management
Flow Cytometry
Primary Care

COULTER® S-CAL® Calibrator Accuracy

The International Council for Standardization in Haematology (ICSH) and the National Committee for Clinical Laboratory Standards (NCCLS) have published methods which are recognized worldwide for the determination of accurate measurements.

A reference method is defined by the ICSH as "a clearly and exactly described technique for a particular determination which, in the opinion of a defined authority, provides sufficiently accurate and precise laboratory data for it to be used to access the validity of other laboratory methods for this determination. The accuracy of the reference method must be established by comparison with a definitive method where one exists. A reference method should be traceable to a primary metrological standard and the degree of inaccuracy and imprecision must be stated."[1] Metrological standards are not available for all hematology measurements.

REFERENCE METHODS

Beckman Coulter uses the following reference methods, which encompass the recommendations of the ICSH[1] and approved standards of the NCCLS.[2,3]

- White Blood Cell Count (WBC)
  A 1:500 dilution in COULTER® ISOTON® II diluent using a 100 µL TC pipette, 0.5 mL COULTER® ZAP-OGLOBIN™ lytic reagent and a 50 mL Class A volumetric flask. Counting is done on a COULTER® Z™ Series instrument† with a lower threshold of 35 fL. Counts are corrected for coincidence.

- Red Blood Cell Count (RBC)
  A 1:100,000 dilution in ISOTON II or COULTER® ISOTON® III diluent using a 10 µL TC pipette and a 1000 mL Class A volumetric flask. Counting is done on a Z Series instrument† with a lower threshold of 25 fL. Counts are corrected for coincidence.

- Hemoglobin (Hgb)
  A 1:250 dilution in NCCLS[2] recommended reagent for the hemiglobincyanide (cyanmethemoglobin) method using a 200 µL TC pipette and 50 mL Class A volumetric flask. Readings are made at 504, 540, and 750 nm. Hgb is calculated using millimolar extinction coefficient.

- Mean Cell Volume (MCV)
  A value is obtained from the RBC and from the measurement of packed cell volume (PCV) by microhematocrit determination without a correction for trapped plasma. The calculation is:
  MCV (fL) = PCV/RBC per NCCLS standard H7-A3[3].

† Assumes Z Series instrument with 100 µm x 75 µm aperture and 500 µL manometer volume settings.

- Platelet (Plt)
  A 1:101 dilution is made using a 20 µL TC pipette and 2 mL of 1% filtered ammonium oxalate. The dilution is plated onto a clean, dry Neubauer ruled phase-type hemacytometer. The hemacytometer is left for approximately 10 minutes in a humidified chamber. Using phase contrast illumination, the platelets in the entire square millimeter on both sides of the hemacytometer are counted. The two counts are averaged and multiplied by 1010.

ASSESSMENT OF ACCURACY

S-CAL calibrator was introduced by Beckman Coulter in 1982 to provide an alternative to whole-blood reference methods. With S-CAL calibrator, laboratories no longer need to perform procedures which are tedious and expensive.

S-CAL calibrator assigned values are routinely reviewed against assessments of whole-blood values, data from the Beckman Coulter Interlaboratory Quality Assurance Program (IQAP), and other data collected to support the accuracy of the assigned values. The values below represent the 95% confidence limits for whole blood samples.

	Mean Value	95% Confidence
WBC	6.4 x 10^3/µL	1.8%
RBC	5.14 x 10^6/µL	0.6%
Hgb	14.9 g/dL	1.0%
MCV	84.8 fL	0.9%
Plt	234 x 10^3/µL	6.0%

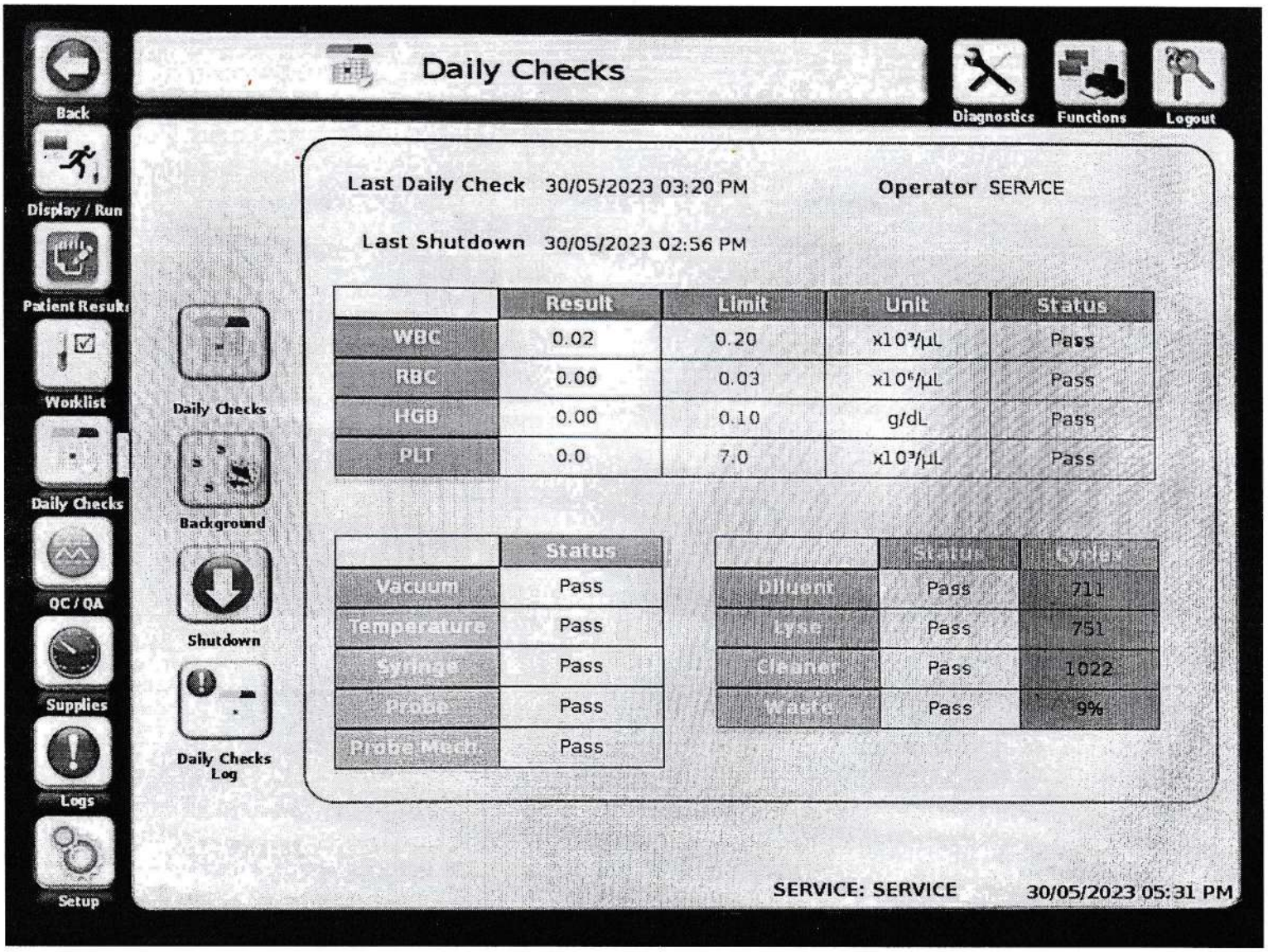
The S-CAL calibrator assigned values are periodically adjusted to maintain 95% confidence limits. Beckman Coulter control assigned values reflect the S-CAL calibrator accuracy at the time they are assayed.

REFERENCES

1. International Council for Standardization in Haematology. Reference method for the enumeration of erythrocytes and leukocytes. Clin Lab Haemat, 1994, 16(2):131-138.

2. NCCLS. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. NCCLS document H15-A3. NCCLS. 940 West Valley Road, Suite 1400, Wayne, Pennsylvania, USA 2000.

3. NCCLS. Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third Edition. NCCLS document H7-A3. NCCLS. 940 West Valley Road, Suite 1400, Wayne, Pennsylvania, USA 2000.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Worklist
Daily Checks
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Supplies
Logs
Setup
Diagnostics
Functions
Logout
Daily Checks
Background
Shutdown
Daily Checks Log
Last Daily Check 30/05/2023 03:20 PM
Operator SERVICE
Last Shutdown 30/05/2023 02:56 PM
Result
Limit
Unit
Status
WBC 0.02 0.20 x10³/µL Pass
RBC 0.00 0.03 x10⁶/µL Pass
HGB 0.00 0.10 g/dL Pass
PLT 0.0 7.0 x10³/µL Pass
Status
Vacuum Pass
Temperature Pass
Syringe Pass
Probe Pass
Probe Mech Pass
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Diluent Pass 711
Lyse Pass 751
Cleaner Pass 1022
Waste Pass 9%
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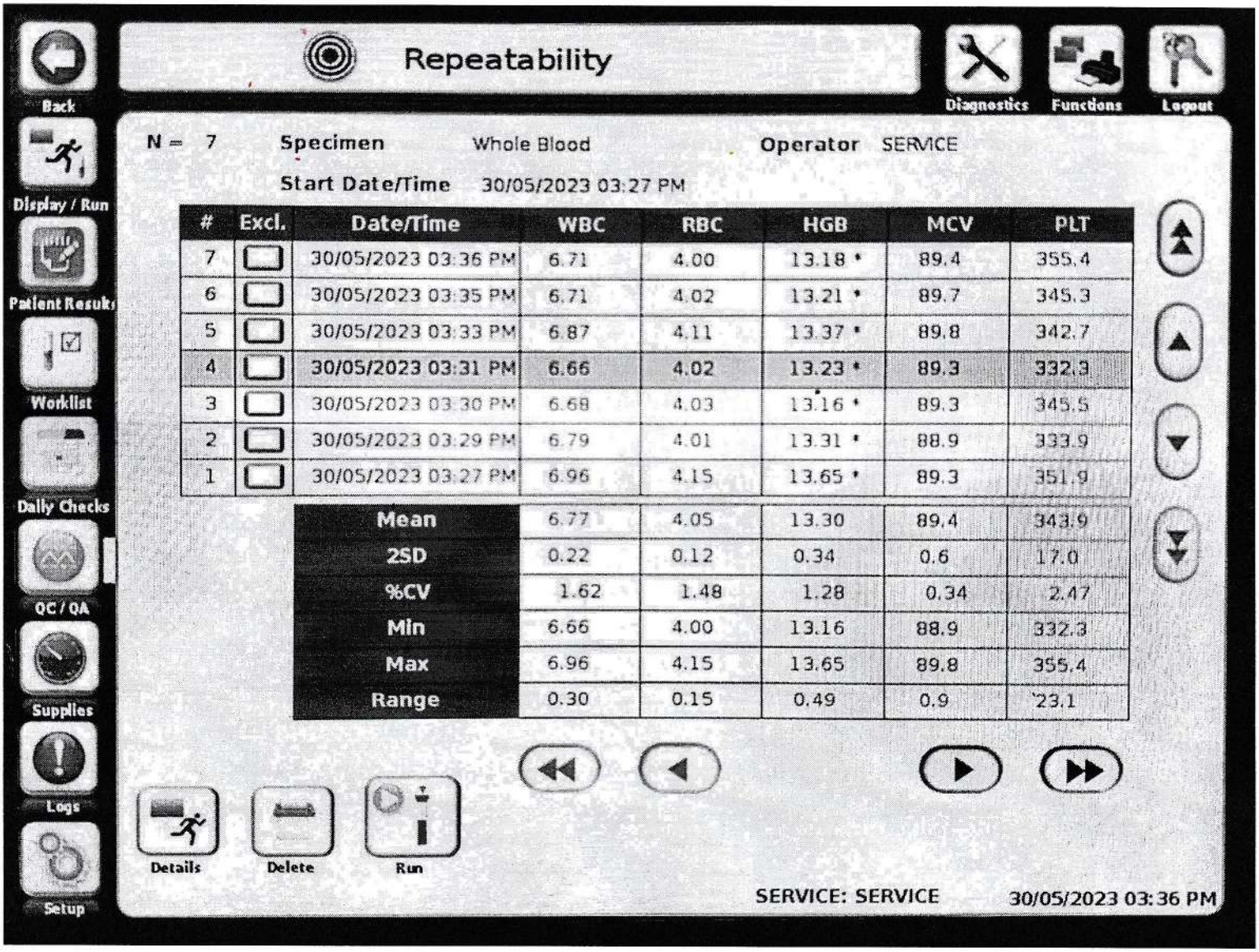
Repeatability
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Diagnostics
Functions
Logout
Display / Run
Patient Results
Worklist
Daily Checks
QC / QA
Supplies
Logs
Setup
N = 7
Specimen Whole Blood
Operator SERVICE
Start Date/Time 30/05/2023 03:27 PM
Excl. Date/Time WBC RBC HGB MCV PLT
7 30/05/2023 03:36 PM 6.71 4.00 13.18 * 89.4 355.4
6 30/05/2023 03:35 PM 6.71 4.02 13.21 * 89.7 345.3
5 30/05/2023 03:33 PM 6.87 4.11 13.37 * 89.8 342.7
4 30/05/2023 03:31 PM 6.66 4.02 13.23 * 89.3 332.3
3 30/05/2023 03:30 PM 6.68 4.03 13.16 * 89.3 345.5
2 30/05/2023 03:29 PM 6.79 4.01 13.31 * 88.9 333.9
1 30/05/2023 03:27 PM 6.96 4.15 13.65 * 89.3 351.9
Mean 6.77 4.05 13.30 89.4 343.9
2SD 0.22 0.12 0.34 0.6 17.0
%CV 1.62 1.48 1.28 0.34 2.47
Min 6.66 4.00 13.16 88.9 332.3
Max 6.96 4.15 13.65 89.8 355.4
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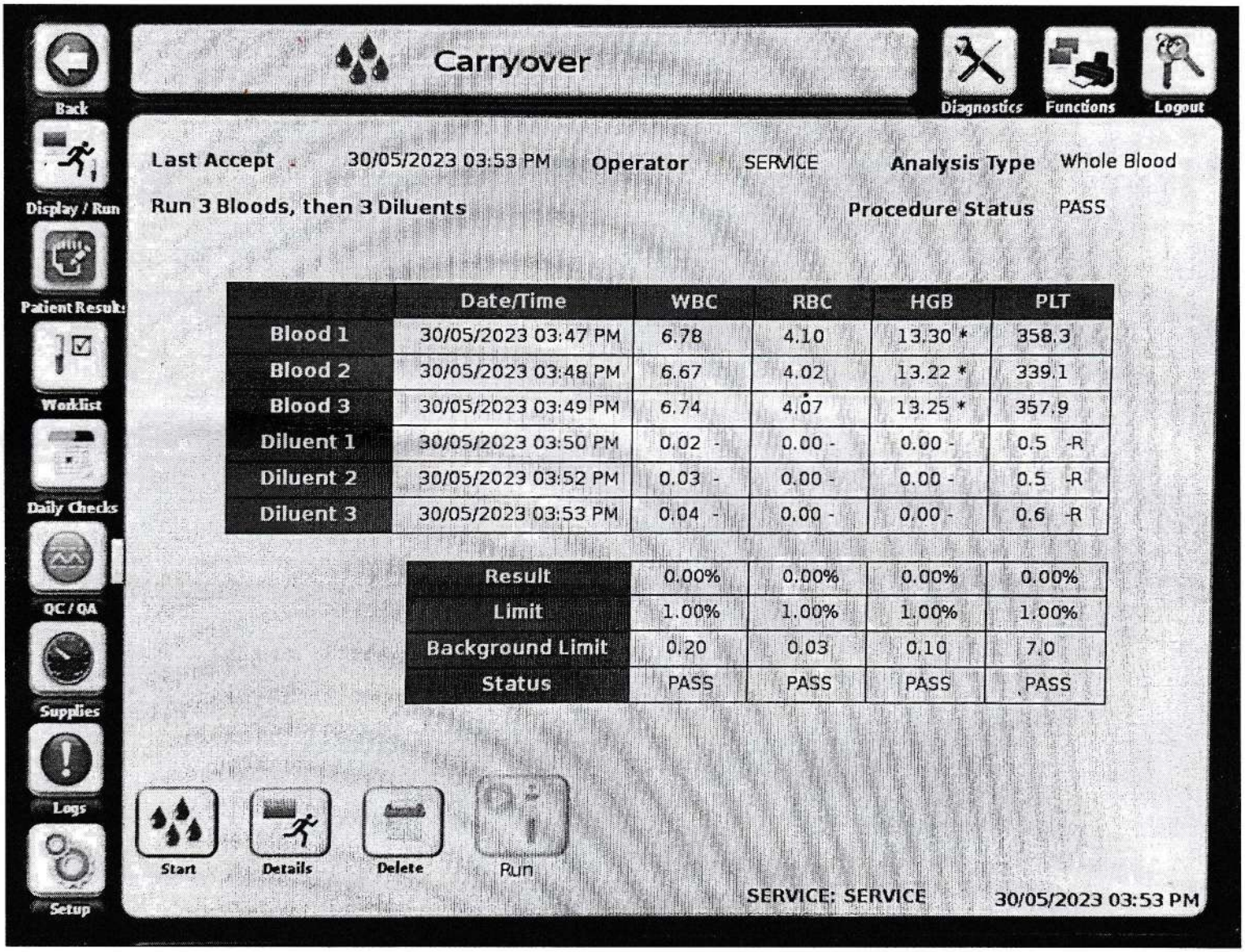

	Date/Time	WBC	RBC	HGB	PLT
Blood 1	30/05/2023 03:47 PM	6.78	4.10	13.30 *	358.3
Blood 2	30/05/2023 03:48 PM	6.67	4.02	13.22 *	339.1
Blood 3	30/05/2023 03:49 PM	6.74	4.07	13.25 *	357.9
Diluent 1	30/05/2023 03:50 PM	0.02 -	0.00 -	0.00 -	0.5 -R
Diluent 2	30/05/2023 03:52 PM	0.03 -	0.00 -	0.00 -	0.5 -R
Diluent 3	30/05/2023 03:53 PM	0.04 -	0.00 -	0.00 -	0.6 -R

Result	0.00%	0.00%	0.00%	0.00%
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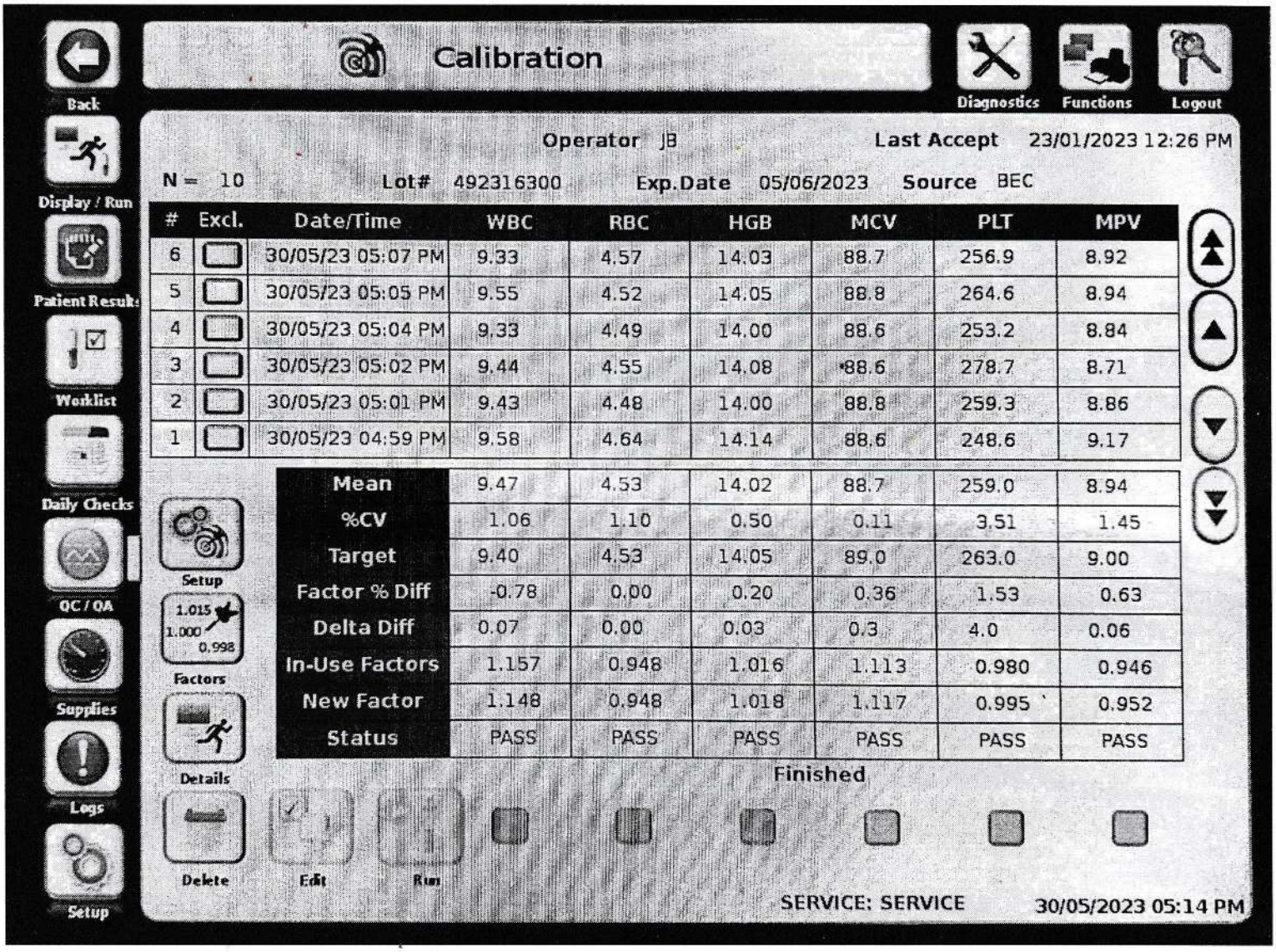
Background Limit	0.20	0.03	0.10	7.0
Status	PASS	PASS	PASS	PASS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Back
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Display / Run
Patient Results
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QC / QA
Supplies
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Last Accept 23/01/2023 12:26 PM
N = 10
Lot# 492316300
Exp.Date 05/06/2023
Source BEC
Excl. Date/Time WBC RBC HGB MCV PLT MPV
6 30/05/23 05:07 PM 9.33 4.57 14.03 88.7 256.9 8.92
5 30/05/23 05:05 PM 9.55 4.52 14.05 88.8 264.6 8.94
4 30/05/23 05:04 PM 9.33 4.49 14.00 88.6 253.2 8.84
3 30/05/23 05:02 PM 9.44 4.55 14.08 88.6 278.7 8.71
2 30/05/23 05:01 PM 9.43 4.48 14.00 88.8 259.3 8.86
1 30/05/23 04:59 PM 9.58 4.64 14.14 88.6 248.6 9.17
Mean 9.47 4.53 14.02 88.7 259.0 8.94
%CV 1.06 1.10 0.50 0.11 3.51 1.45
Target 9.40 4.53 14.05 89.0 263.0 9.00
Factor % Diff -0.78 0.00 0.20 0.36 1.53 0.63
Delta Diff 0.07 0.00 0.03 0.3 4.0 0.06
In-Use Factors 1.157 0.948 1.016 1.113 0.980 0.946
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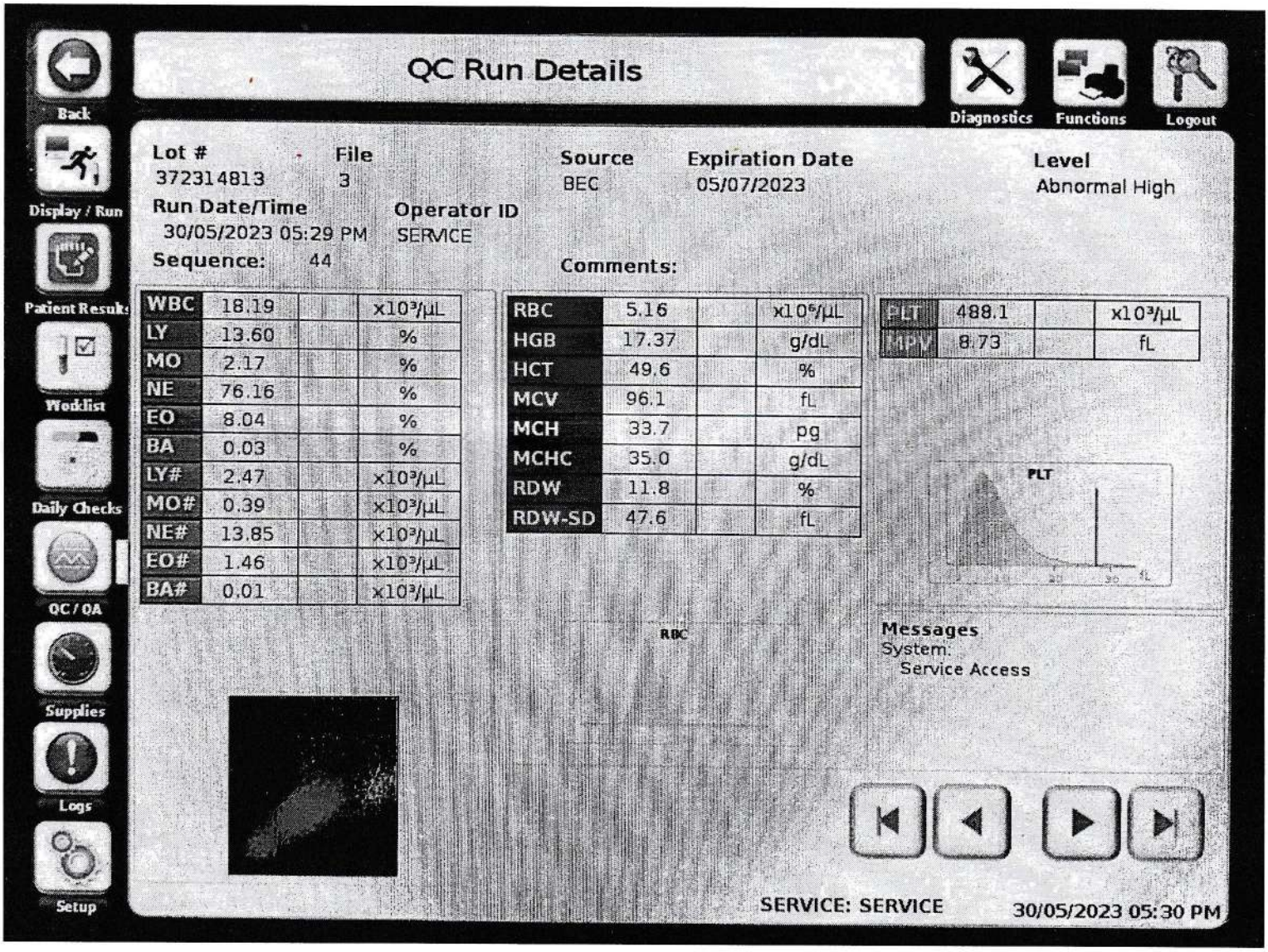
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372314813
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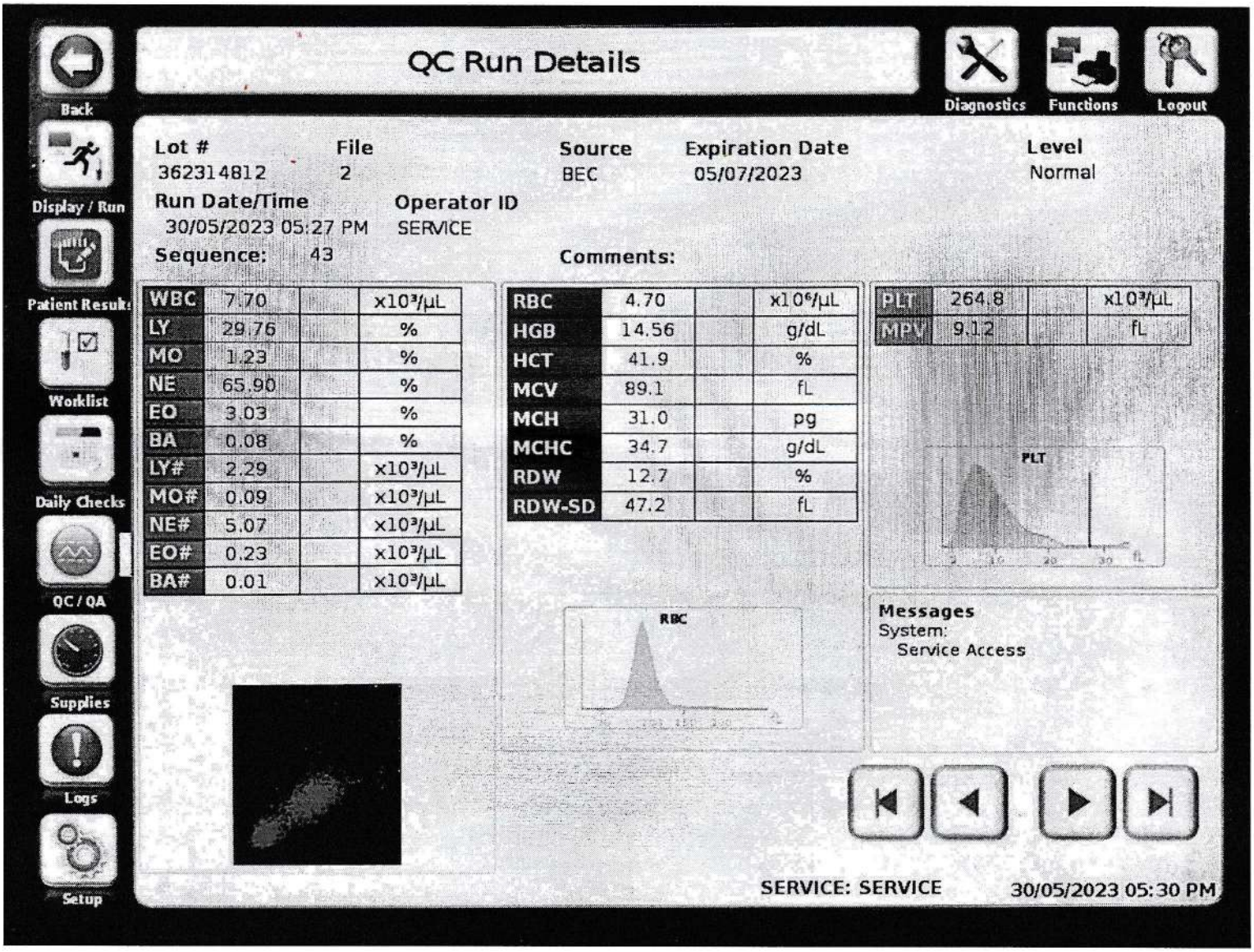
3
Source
BEC
Expiration Date
05/07/2023
Level
Abnormal High
Run Date/Time
30/05/2023 05:29 PM
Operator ID
SERVICE
Sequence:
44
Comments:
WBC 18.19 x10³/µL
LY 13.60 %
MO 2.17 %
NE 76.16 %
EO 8.04 %
BA 0.03 %
LY# 2.47 x10³/µL
MO# 0.39 x10³/µL
NE# 13.85 x10³/µL
EO# 1.46 x10³/µL
BA# 0.01 x10³/µL
RBC 5.16 x10⁶/µL
HGB 17.37 g/dL
HCT 49.6 %
MCV 96.1 fL
MCH 33.7 pg
MCHC 35.0 g/dL
RDW 11.8 %
RDW-SD 47.6 fL
PLT 488.1 x10³/µL
MPV 8.73 fL
PLT
RBC
Messages
System:
Service Access
SERVICE: SERVICE
30/05/2023 05:30 PM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362314812
File
2
Source
BEC
Expiration Date
05/07/2023
Level
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Run Date/Time
30/05/2023 05:27 PM
Operator ID
SERVICE
Sequence: 43
Comments:
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LY 29.76 %
MO 1.23 %
NE 65.90 %
EO 3.03 %
BA 0.08 %
LY# 2.29 x10³/µL
MO# 0.09 x10³/µL
NE# 5.07 x10³/µL
EO# 0.23 x10³/µL
BA# 0.01 x10³/µL
RBC 4.70 x10⁶/µL
HGB 14.56 g/dL
HCT 41.9 %
MCV 89.1 fL
MCH 31.0 pg
MCHC 34.7 g/dL
RDW 12.7 %
RDW-SD 47.2 fL
PLT 264.8 x10³/µL
MPV 9.12 fL
PLT
RBC
Messages
System:
Service Access
SERVICE: SERVICE
30/05/2023 05:30 PM

QC Run Details

Back | Display / Run | Patient Results | Worklist | Daily Checks | QC / QA | Supplies | Logs | Setup

Diagnostics | Functions | Logout

Lot # 352314811 **File** 1 **Source** BEC **Expiration Date** 05/07/2023 **Level** Abnormal Low

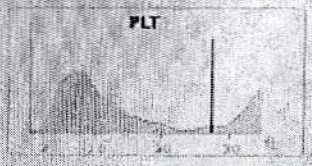
Run Date/Time 30/05/2023 05:24 PM **Operator ID** SERVICE

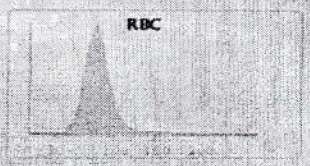
Sequence: 42 **Comments:**

WBC	2.77		x10³/µL
LY	45.26		%
MO	1.78		%
NE	41.82		%
EO	11.06		%
BA	0.08		%
LY#	1.25		x10³/µL
MO#	0.05		x10³/µL
NE#	1.16		x10³/µL
EO#	0.31		x10³/µL
BA#	0.00		x10³/µL

RBC	2.40		x10⁶/µL
HGB	6.59		g/dL
HCT	18.9		%
MCV	78.9		fL
MCH	27.5		pg
MCHC	34.9		g/dL
RDW	14.3		%
RDW-SD	45.5		fL

PLT	80.6		x10³/µL
MPV	9.57		fL





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Service Access

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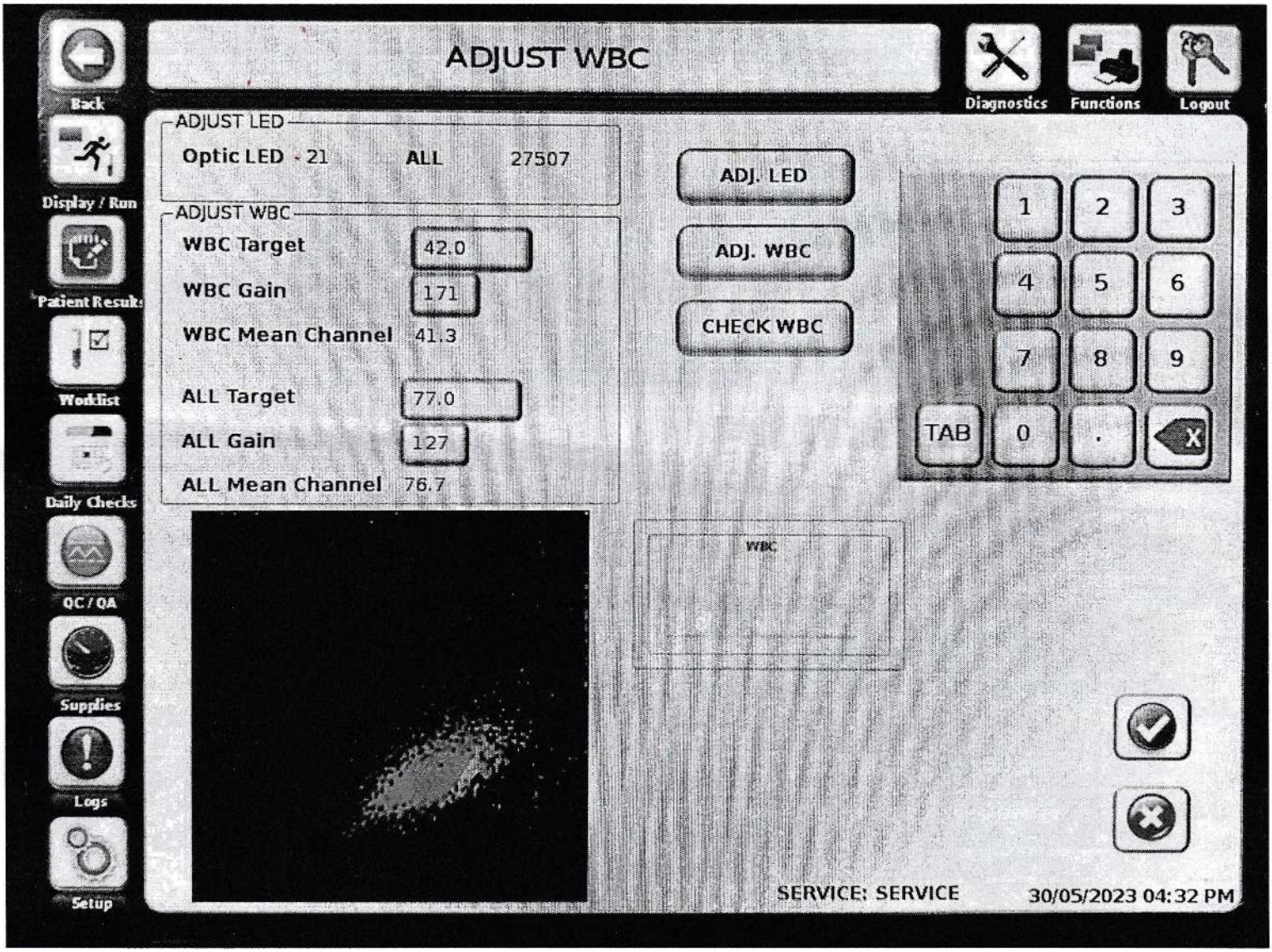
ADJUST WBC
Back
Diagnostics
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Logout
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Patient Results
Worklist
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Supplies
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Setup
ADJUST LED
Optic LED 21
ALL 27507
ADJUST WBC
WBC Target 42.0
WBC Gain 171
WBC Mean Channel 41.3
ALL Target 77.0
ALL Gain 127
ALL Mean Channel 76.7
ADJ. LED
ADJ. WBC
CHECK WBC
1 2 3
4 5 6
7 8 9
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WBC
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30/05/2023 04:32 PM