ARK Diagnostic System Pvt. Ltd.

Arksys/Ser/0211/2020

Date: - 4th February,2020

CALIBRATION CERTIFICATE

This is to certify that the Semi Automated Hematology Cell Counter Model ABACUS JUNIOR BASIC bearing Sr.No. 140271 supplied to S.S.Hospital (PETLAD) is under maintenance contract with us. .

We confirm that the said instrument has been provided the regular maintenance service and calibrated with Calibrator (DiatroCal) Lot No. 100-1119 on 3rd FEBRUARY, 2020 as per the necessary norms.

We also confirm that this calibration is valid for one year from the date, by which time it has to be serviced again by our authorized service engineer.

Yours Faithfully,

For Ark *Diagnostic System Pvt. Ltd.*,

(Technical Service Department)

DIATRON MI PLC
PAPIRGYAR 58-59, H-1038 BUDAPEST, HUNGARY,
TEL:+361 4369800; www.diatron.com

Subject: **Traceability of DiatroCal Calibrator Assay Process to Reference Methodology**
Standard: **EN ISO 17511:2003 E**

Summary: The process for generation of assay results for Diatron control & calibrator products satisfies the requirements stated in Standard EN ISO 17511 E. The appropriate metrological traceable chain is "Cases with international convention reference measurement procedure (which is not primary) but no international convention calibrator and without metrological traceability to SI". (see EN-ISO 17511:2003 E. page 21, section 5.4.

Hematology Reference Methods
Hematology analyzers in Diatron Measurement Technology Laboratory are traceable to whole blood calibration obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

WBC
A 1:500 dilution is prepared using a 200 mL Class A volumetric flask filled with isotonic diluent. 2.4 mL of diluent is removed. Sample is added to the flask using a 400 mL T.C. micropipet, followed by 2.0 mL lysing agent. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

RBC
A 1:50,000 dilution is prepared using a 1000 mL Class A volumetric flask filled with isotonic diluent. Sample is added to the flask using a 20 mL T.C. micropipet. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

HGB
A 1:251 dilution is prepared using a 100 mL Class A volumetric flask filled with the NCCLS recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (1). Sample is added to the flask using a 400 mL T.C. micropipet. The sample is filtered with a 0.2 µm filter immediately before reading. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to NCCLS H15-A3 and ICSH recommendations (1).

HCT
Plain glass microhematocrit tubes (not coated with anticoagulant) are filled with sample, sealed with sealing putty and centrifuged for 5 minutes in a microhematocrit centrifuge according to the NCCLS H7-A3 document (2). After centrifugation, the length of the whole column including the plasma, and the length of the red blood cell column, are viewed and measured using a microscope with graduated stage and an ocular micrometer. The hematocrit (packed cell volume) is calculated as the ratio of the two measurements. No correction is made for trapped plasma.

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MCV

On some instruments MCV is the calibrated parameter instead of the HCT. The MCV is calculated from the HCT and RBC using the formula:

$MCV = HCT \times 10/RBC$

PLT

A 1:126 dilution is prepared using a 50 mL Class A volumetric flask filled with filtered 1% ammonium oxalate. Sample is added to the flask using a 400 mL T.C. micropipet. The dilution is plated onto a clean, dry Neubauer ruled phase type hemocytometer. The hemocytometer is left for 10 minutes in a humidified chamber. Using phase contrast optics, the platelets in the entire central square millimeter on both sides of the hemocytometer are counted. The two counts are averaged and multiplied by 1260 (dilution factor 126 × volume factor 10 = 1260).

References

1. 1. National Committee for Clinical Laboratory Standards. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood: Approved Standard-Third Edition. NCCLS document H15-A3. Wayne, PA: NCCLS, 2000.
2. 2. National Committee for Clinical Laboratory Standards. Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard, NCCLS document H7-A3. NCCLS, Wayne, PA: NCCLS, 2001.