R&D SYSTEMS
a bio-techne brand

AIS168-004 Rev. 10/17

HC WBC Diff

HEMATOLOGY CONTROLS

CONTROL

LOT HD1218

2019-02-05

QCP Data Months: DEC, JAN

Instrument	LEVEL 1 (LOW) LOT HD12181		LEVEL 2 (NORMAL) LOT HD12182		LEVEL 3 (HIGH) LOT HD12183	
HemoCue® WBC DIFF	Assay Mean	Expected Range	Assay Mean	Expected Range	Assay Mean	Expected Range
WBC X 10^9/L	3.2	2.2 - 4.2	8.0	6.0 - 10.0	18.2	15.2 - 21.2
NEU X 10^9/L	0.8	0.2 - 1.4	2.2	0.7 - 3.7	7.8	3.6 - 12.0
NEU %	24	6 - 42	28	10 - 46	43	20 - 66
LYM X 10^9/L	1.2	0.6 - 1.8	3.0	1.8 - 4.2	6.2	2.9 - 9.5
LYM %	39	21 - 57	38	23 - 53	34	16 - 52
MON X 10^9/L	0.2	0.0 - 0.4	0.3	0.0 - 0.6	0.7	0.0 - 1.4
MON %	5	0 - 10	4	0 - 8	4	0 - 8
EOS X 10^9/L	0.9	0.4 - 1.4	2.1	0.8 - 3.4	2.9	0.7 - 5.1
EOS %	27	13 - 41	26	11 - 41	16	4 - 28
BAS X 10^9/L	0.2	0.0 - 0.4	0.3	0.0 - 0.6	0.5	0.0 - 1.0
BAS %	5	0 - 10	4	0 - 8	3	0 - 6

INTENDED USE

HC WBC Diff Control is an assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood. Refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

HC WBC Diff Control is an in vitro diagnostic reagent composed of human erythrocytes and leukocytes suspended in a plasma-like fluid with preservatives.

⚠ PRECAUTION

HC WBC Diff Control is intended for ***in vitro*** **diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL. For in vitro diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at: *http://www.rndheme.com/TechnicalInformation.aspx*

No test method can offer complete assurance that infectious agents are absent; therefore, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.