INSTRUCTIONS FOR PARTICIPANTS

Hematology Basic – HM11014 **PT Round No.:** ----------
Opening Date: month/date/year **Result Deadline Date:** month/date/year (midnight 12:00 IST)
UPN: ---------- **User Name:** ---------- **Password:** ----------

Intended Use:

To provide an independent and confidential third-party Proficiency Testing (PT) of individual laboratory performance to promote a continuous improvement of the quality. The EQAsure Hematology Basic PT program is primarily intended for public and private hospitals and clinical laboratories using automated analysers for Hematology testing. Manual testing methods are not acceptable.

Analytes:

WBC (White Blood Cells), RBC (Red Blood Cells), HGB (Hemoglobin), HCT (Hematocrit), MCV (Mean Corpuscular Volume), MCH (Mean Cell Hemoglobin), MCHC (Mean Cell Hemoglobin Concentration), PLT (Platelets), MPV (Mean Platelet Volume), RDW-SD (Red Blood Cell Distribution Width-SD), RDW-CV (Red Blood Cells Distribution Width-CV).

PT Item:

Ready to use PT item contains human whole blood.

Subcontracted Activity:

Homogeneity and Stability testing of PT item is subcontracted to competent subcontractor.

Storage and Stability:

The PT item is shipped with cool bags. Upon arrival of PT item, store it at 2-8°C in vertical position. Do not overheat (>25 °C) and do not freeze (below 0 °C) PT item. Being temperature sensitive item once received, PT item shall not be return back to PT provider in any circumstance, unless it is asked for. The PT item will be stable until the expiration date, when stored unopened.

Material Required but Not Provided:

Analyser and reagents required to perform assay.

Timing of Assay:

Participants will receive PT item at pre-defined time period. Test PT item within 3 days of arrival at participant laboratory. Kindly refer to “Calendar of Program Events” to get information about dispatched month of PT item for testing and deadline date of result to be submitted on web portal. Each PT item is labeled with lot number, month of PT item use and expiry date. Participants have to use appropriate PT item as per the schedule.

Procedure for Sampling and Analysis:

Preparation:

Remove the tubes from the refrigerator and allow it to reach at room temperature (15-25°C) before mixing. Do not mix on a mechanical mixer.

Gently invert the tube back and forth by holding between thumb and fore finger for 8-10 times before sampling, but do not shake it. Continue to mix in this manner until the blood cells are completely suspended (No blood cells shall remain settled in the bottom of tube). The PT item should be treated and analyzed same as patient sample.

Analysis:

Participants are free to use methods/analyser of their choice.

Analyze the PT item in accordance with instructions provided in operation manual of the analyser.

a) Automatic sample handling: Remove the tube from the sample handler immediately after sampling.

b) Manual sample handling: Carefully wipe the rim of the tube and cap with a lint free tissue and replace the cap. Return the tube to the refrigerator within 30 minutes after use.

PT Results:

The measured values of each analyte must be submitted on web portal on or before midnight 12:00 IST on of deadline date of result submission.

Refer “Participant Manual” for more information available on EQAsure web portal. Results shall be submitted in the "Result” section on web portal.

Care must be taken to report concentration of each analyte in the units of measurement available on web portal; the laboratory that uses different units must convert its results using appropriate conversion factor before submitting results.

Performance Evaluation and Reports:

Results of participant received before the result deadline date specified in the "Calendar of Program Events" for particular round are included in the analysis.

After deadline date of result submission, all results are evaluated as per statistical method described in ISO 13528, algorithm A, Annex C for their performance evaluation. At the end of each evaluation, participants will get summary report for all analytes as well as report for individual analyte showing their performance within different group over a period of time along with graphical presentation. All reports are designed as per ISO/IEC17043 requirements.

Late Results:

Late result received after deadline date of result submission are considered as “Late Result” and will be flagged in report as “L”. Participant can request to open window for late result submission from result menu within 48 h after deadline date of result submission.

Bio-safety:

PT item being derived from human origin should be considered potentially infectious and should be handled with the same precautions as patient sample.

Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with large volume of water. In case of contact with eyes or if ingested, seek immediate medical attention.

The residual PT item remaining after testing must be decontaminated and disposed of in-compliance with the local regulations of waste disposal.

Limitation:

The PT item should not be used past the expiration date. This PT item is not intended for use as a standard.

After mixing, the PT item should be similar in appearance to whole blood. In unmixed tubes, the supernatant may appear cloudy and/or reddish. This is normal and does not indicate deterioration. Other discoloration, very dark and red supernatant or unacceptable result may indicate deterioration. Do not use the PT item if deterioration is suspected.

The performance of this PT item is assured only if it is properly stored and used as described in the Instruction for Participant. Incomplete mixing of PT item tube before use affects PT item use for testing and remaining PT item.

Confidentiality:

EQAsure is committed to maintain confidentiality for each participant. To protect the privacy of each participant assigned an Unique Participant Number (UPN), which is known only to EQAsure and the participant. The EQAsure shall not disclose the participants details to any third party, unless required by regulatory authority and/or accreditation bodies without the prior permission of the participants.

Collusion between participants is not allowed. To prevent collusion of result, participant should not share or discuss their results with other participants. EQAsure reserves the right to disqualify any participating laboratory from PT scheme if there is evidence of falsification or collusion with another participating laboratory.

Support:

All participants can contact our support team during working hours for administrative, technical, scientific or organizational information at +91 7096119992 and by e-mail at pmt@fugenbiomed.com.

Next Survey Details:

Dispatch Month	Sample No.	HM11041	Opening Date	Result Deadline Date	Report Issue Date

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
	Consult instructions for participants		Catalog Number		Lot
	Temperature Limitation		Expiration Date		Manufacture

Limited Expressed Warranty Disclosure

FUGEN BIOMED PVT., LTD. limits the warranty to the PT item in as much as the said PT item will function only within the limitations and specification as described in the Instructions for Participants. Any deviation there from by the purchaser or the end user shall not be the liability and/or responsibility of FUGEN BIOMED PVT., LTD. FUGEN BIOMED PVT., LTD. shall not be liable and/or responsible for any misuse of the said PT item after the date of expiry. If any defect is proved in manufacture of the PT item, FUGEN BIOMED PVT., LTD. shall be liable only to the extent of the replacement of the said PT item or refund of its purchase price thereof and shall not be liable for any consequential loss arising there from.

Analytes and Reporting Unit:

Analytes	Reporting Unit	Analytes	Reporting Unit	Analytes	Reporting Unit
WBC	$10^3/\mu L$	MCHC	g/dL	MPV	fL
HGB	g/dL	RBC	$10^6/\mu L$	RDW-SD	fL
MCH	pg	PLT	$10^3/\mu L$	RDW-CV	%
MCV	fL	HCT	%		

Fugen Biomed Pvt., Ltd.
No. 104, Dharmabhakti Complex,
Khushalwadi, Jamalpore,
Navsari – 396445, Gujarat, India

Customer Care Contact Details
+91 909 909 5565
contact@fugenbiomed.com
www.fugenbiomed.com