INSTRUCTIONS FOR PARTICIPANTS – HEMATOLOGY BASIC	FORMAT NO.	FB/EQA/FR/008
	D.P NO.	FB/EQA/DP/012
	REV. NO.	03
	DATE	07/01/2025
Ref.: ISO 17043 – 2023 CL. No.: 7.3.5	SHEET	1 of 4

Hematology Basic – HM11041					
Opening Date:	month/date/year	**PT Round No.:**		**Lot No:**	
UPN:		**Result Deadline Date:**	month/date/year (midnight 12:00 IST)	**Report Issue Date:**	

Intended Use:

To provide an independent and confidential Proficiency Testing (PT) of individual laboratory performance to promote a continuous improvement of the quality. The EQAsure Hematology Basic PT scheme is primarily intended for hospitals and clinical laboratories using automated analysers for Hematology testing.

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.

Externally Provided Activity:

Homogeneity and Stability testing of PT item.

Storage

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. PT item should be protected from the direct light during storage. The PT item is stable until the expiration date, when stored unopened.

Timing of Assay:

Participants will receive PT item at pre-defined time period. It is recommended to test the PT item as soon as possible after receipt. 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 vial 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 Preparation and Analysis:

Preparation:

Remove the vial 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).

Analysis:

Participants are free to use methods/analyser of their choice. The PT item should be treated and analyzed same as patient sample. 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 item shall not be return back to PT provider unless it is asked for.

PT Results:

Participants have to test PT items by themselves only and are not allowed to utilise external service providers for the same. The participants are advised to keep record of all calculations, graphs and other raw data to demonstrate that PT item testing is done by them in their premises. The failure of participation laboratory to provide above information any time as asked by EQAsure may lead to results not considered/disqualify participation from PT scheme and decision of EQAsure in this regard shall be final. EQAsure is not seeking this information along with PT reports but may ask for the same if required.

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

Results shall be submitted in the "Result" section on web portal. Refer "Participant Manual" for initiating request for late result and amendment in results.

Care must be taken to report the result 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:

After deadline date of result submission, result received from participants is recorded, analysed and evaluated by valid methods as described in ISO 13528 standard. At the end of each round, participants will get summary report for all analytes as well as report for individual analyte showing their performance along with graphical presentation. All reports are designed as per ISO 17043 requirements.

Bio-safety:

PT item 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.

Factor Affecting Measurement Results:

The PT item should not be used past the expiration date.

It is recommended to store the PT item at recommended temperature as mentioned in "Storage" section.

Participant shall use PT item for analytes mentioned in "Analyte" section.

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 before use affects PT item use for testing and remaining PT item.

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.

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. Participant results and reports are confidential and only accessible by participant laboratory in their login account. A participant laboratory does not have access to the details of other participants. All details supplied by participants to EQAsure is kept confidential. EQAsure will not disclose the participants identity without the prior permission of the participants to public domain, unless required by regulatory authority and/or accreditation bodies. Participant specific information will not be shared in public domain, if required to share prior permission from participants will be taken. Participant details and performance will be shared to accreditation bodies and regulatory authorities without prior permission of participants, when asked. An authorized person will deal with all communications from participants and reasonable confidentiality will be maintained. For non-disclosure of any information that would breach the confidentiality, staff members have signed the confidentiality agreement.

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.

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.

Number of digits before and after decimal point in result entry:

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter	
			Before Decimal (Maximum)	After Decimal (Maximum)
WBC	$10^3/\mu L$	$10^3/\mu L$	3	2
	$10^9/L$		3	2
	$10^3/mm^3$		3	2
RBC	$10^6/\mu L$	$10^6/\mu L$	1	2
	$10^{12}/L$		1	2
	10^6/mm3		1	2
HGB	g/dL	g/dL	2	1
	g/L		3	1
	mmol/L		2	2
HCT	%	%	2	1
	L/L		1	3
MCV	µm3	fL	3	1
	fL		3	1
MCH	pg	Pg	2	1
	fL		1	2
MCHC	g/dL	g/dL	2	1
	g/L		3	1
	mmol/L		2	1
PLT	$10^3/\mu L$	$10^3/\mu L$	3	1
	$10^9/L$		3	1
	$10^3/mm^3$		3	1
MPV	fL	fL	2	1
	μm^3		2	1
RDW-SD	fL	fL	2	1
RDW-CV	%	%	2	1

Next Round Details:

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

Symbol Key:

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
	Consult instructions for participants		Catalog Number		Temperature Limitation		Biohazard

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