bio-techne[®]

HEMATOLOGY ANALYSER VALIDATION WHAT THE ISO 15189 STANDARD SAYS ABOUT VERIFICATION OF

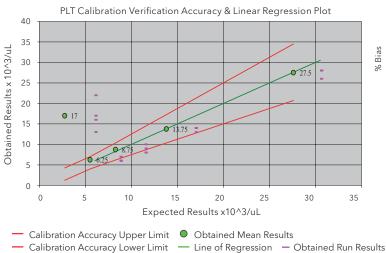
ANALYTICAL PROCEDURES

The ISO 15189 Standard, effective since 1st March 2016, requires validated examination procedures to be independently verified by the laboratory before being used regularly (§5.5.1.2).

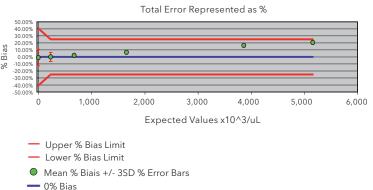
CBC-LINE kits are used in combination with independently verified and documented calibration, the information can be used to establish the range of lowest and highest values that can be accurately reported by the hematology analyser. Each kit includes one Instrument Evaluation Report at no extra charge.



CHECK THE QUANTIFICATION LIMITS OF YOUR ANALYSER



CALCULATION OF UNCERTAINTY ON YOUR MEASUREMENT DOMAIN



LINEARITY KITS (CBC-LINE) MEASURE AND VERIFY:

The field of analysis for WBC, RBC, HGB, HCT, PLT and Reticulocytes :

- Detection limit
- Linearity
- Measurement domain

Total error calculated on 12 concentration levels :

- Repeatability
- Accuracy
- Fidelity
- Uncertainty measurement

ESTABLISH REPORTABLE RANGES OF YOUR HEMATOLOGY ANALYSERS

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