

5.5.3 → Documentation of examination procedure

- purpose of examination
 - Required equipment & reagents
 - Environmental & safety controls
 - Calibration procedures (metrological traceability)
 - Quality control procedures
 - principle & method of procedure used
 - procedural steps
 - Interferences (lipemia, Hemolysis, drugs, bilirubinemia)
 - Biological reference intervals or clinical decision values
 - Reportable interval of examination results
 - alert/critical values where appropriate
 - Laboratory clinical interpretation
 - potential source of variation
 - References
 - Principle of procedure for calculating results
 - Instruction for determining quantitative results when result is not within measurement interval
 - Type of sample (serum, urine, plasma)
 - Patient preparation
 - Type of container & additives
- written in language commonly understood by staff in laboratory
- be available in appropriate location