SANAS Laboratory Accreditation Process
10th Largest Accreditation Body
Approximately 1350 Accredited Facilities
SANAS Main Scope of Accreditation

• **Laboratories**
  Testing (medical), Calibration

• **Inspection Bodies**
  X ray equipment (DoH)

• **Certification Bodies**
  QMS, EMS, Prod. Cert.
284 Medical Laboratory Accreditations

Main Scopes of Accreditation

Chemistry  Haematology
Microbiology  Serology
TB  Immunology
Virology  Human genetics
Anatomical pathology (Histo. & Cyto.)
SANAS Accreditation

• The definition of an accreditation assessment of a laboratory is:

“an independent assessment (by experts) on the competence of an organisation and/or individual to perform tests/calibrations against a schedule of accreditation”

• Accreditation confirms technical competence
What is accreditation

Accreditation is the recognition that a laboratory can produce “accurate results” within acceptable limits on a consistent and sustainable basis.
Accreditation confirms COMPETENCE
Competence concerning a laboratory

- **Personnel**
- **Methods**
- **Equipment**
- **Measurement traceability**
- **Environment**

There has to be criteria for this competence e.g. Validation of Methods, known measurement relationship (standards, inter-comparisons).
Accreditation is based on competence

Within the ISO 15189 there are system elements and technical elements.

Although both are important the system is secondary to the competency aspects.

An accreditation assessment team will assess back to the accreditation schedule and see that a system is implemented in accordance with ISO 15189 that can support the competency aspects. This is to give an assurance of the maintenance and sustainability of the laboratory’s ability to continue to produce results in accordance with the accreditation schedule.
### SCHEDULE OF ACCREDITATION

**Testing Laboratory Number: M675**

<table>
<thead>
<tr>
<th>Permanent Address of Laboratory: Spear Laboratories Med. CentrePark Hotazel</th>
<th>Signatories: Ms. D. Lawson de Wet : Contact Person Dr. M. Slimjan : Signatories as authorised by the Head of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postal Address: PO Box 232 Hotazel 2243</td>
<td>Issue No. : 4</td>
</tr>
<tr>
<td>Tel : (029) 642 4007</td>
<td>Date of issue : August 2005</td>
</tr>
<tr>
<td>Fax : (019) 642 9965</td>
<td>Expiry date : August 2009</td>
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</table>

<table>
<thead>
<tr>
<th>Materials/Products Tested</th>
<th>Types of Tests/Properties Measured, Range of Measurement</th>
<th>Standard Specifications, Equipment/Techniques Used</th>
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<tbody>
<tr>
<td><strong>HAEMATOLOGY</strong></td>
<td>Full Blood Count</td>
<td>Cell-dyn 3500</td>
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<td></td>
<td>Reticulocytes</td>
<td>Westergren</td>
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<td></td>
<td>ESR</td>
<td>Behring Fibrinometer/Manual</td>
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<td>Differential count</td>
<td>D-Ditest Diagnostica Stago Manual</td>
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<td>PI</td>
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<td>PTT</td>
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<td></td>
<td>D-Dimer</td>
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<td></td>
<td>Malaria smear – thick &amp; thin smears</td>
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<tr>
<td></td>
<td>ICT – Rapid for detection of Plasmodium (positive/negative) falciparum &amp; vivax</td>
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</table>
Through ILAC the internationally recognized requirements for the accreditation of laboratories are:

That the laboratory is competent in meeting their accreditation schedule/scope

&

has a system implemented that meets the criteria of ISO 15189
And

Meets other Internationally accepted accreditation body requirements for that laboratory’s specific activities

(e.g. participation in PT / inter-comparison / EQC schemes, test labs using accredited calibration authorities)
SANAS Assessment Process

Pre-opening meeting (assessors)

Opening meeting

ASSESSMENT

Pre-closing meeting (assessors)

Closing meeting
(SANAS Assessment process)

**ASSESSMENT**

**Lead Assessor**

Manages the assessment process &

Assesses – System and interface with the Technical Aspects records the assessment on checklists based on the requirements of ISO 15189 Non Conformance forms
(SANAS Assessment process)

ASSESSMENT

Technical Assessor(s)

Assesses the competency of the Laboratory

Assesses –Technical Aspects against the schedule of accreditation

records the assessment on Witnessing forms and Vertical assessment forms based on the requirements of ISO 15189

Non Conformance forms
SANAS Assessment process

ASSESSMENT

Technical Assessor(s)

Witnessing forms recording –
What is happening today.

Vertical assessment forms recording-
What happened in the past to assist in making a judgment for the future.
SANAS Assessment process

ASSESSMENT
Technical Assessor(s)

Vertical assessment cuts through the competency aspects.

Personnel
Methods
Equipment
Measurement traceability
Environment

- There has to be criteria for this competence e.g. Method Validation known measurement relationship (standards, inter-comparisons).
Pre-close out meeting

Feedback by all assessors on the competency & support system of the laboratory based on the evidence recorded on the System checklists, Witnessing forms, Vertical assessment forms and the Non conformance reports

RECOMMENDATION
(SANAS Assessment process)

Close out meeting

*Feedback by the assessment team to Laboratory Management on the status of their system and competency to produce acceptable results.*

&

*Recommendation to be forwarded to the SANAS Approvals Advisory Committee*
Clearance of Non Conformances

Either by documentation or on-site clearance in an agreed time period
Final Decision by the SANAS Approvals Advisory Committee
For laboratories to maintain this recognition, conformity assessment bodies are re-evaluated periodically by the accreditation body to:

- ensure their **continued compliance with requirements**; and
- check that their **standard of operation is being maintained**.

The conformity assessment body may also be required to participate in relevant proficiency testing programs between reassessments, as a further demonstration of technical competence.
Within countries Government bodies and regulators are constantly called upon to make decisions related to:

- Protecting the health and welfare of consumers and the public;
- Protecting the environment;
- Developing new regulations and requirements;
- Assessing compliance;
- Allocating resources.

Government bodies and regulators must have confidence in data generated by laboratories and/or inspection bodies to help make these decisions.

Therefore government departments are increasingly making use of accredited conformity assessment bodies to help establish and assure this confidence.
Science finds

Industry applies

*Man conforms* (confirms)