



SADCAS Ref. No:														
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APPLICATION FOR ACCREDITATION OF MEDICAL LABORATORY

PART 1: GENERAL INFORMATION

This form should be completed in full and returned to:

**Southern African Development Community Accreditation Service (SADCAS)
Attention: Technical Manager**

Postal Address:

Private Bag 00320
Gaborone
Botswana
Tel: +267 3132909/ 3132910
Fax: +263 3132922
Email: info@sadcas.org

Physical Address:

Plot 50369, Unit 3A Second Floor
Tholo Office Park, Fairgrounds
Gaborone
Botswana

Please complete ALL applicable sections of the form in CLEAR PRINT or in type.

This form is available in electronic form. Please do not modify the form other than filling in the sections provided for this purpose. Any form that is modified will not be recognized as a valid application. Should you have difficulties in completing the form, please contact SADCAS or the National Accreditation Focal Point office in your country.

If you wish to complete and forward the form by email, please note that SADCAS does not accept responsibility for breach of confidentiality of information or for the receipt of applications. **All applications submitted by email must be forwarded, duly signed, by surface/special courier mail.**

Receipt of payment of the application fee shall be required prior to processing the application.

Note: If you do not receive acknowledgement of receipt of your application from SADCAS or fax within four (4) weeks of dispatch you should contact the SADCAS Office. This application remains valid for one year from the date of application.

Date of Application														
Organization														
VAT Registration No. (where applicable)														
Contact Person										Title				
Position														
Postal Address														
Physical Address														
Tel No:						Direct Tel No:						Fax No:		
Mobile No:							Email address:							
Field of Operation														

Application for: <i>(Tick as appropriate)</i>					
Initial Accreditation <input type="checkbox"/> <i>Proceed to complete Parts 2 – 5</i>		Extension of Accreditation <input type="checkbox"/> <i>Proceed to complete</i> <ul style="list-style-type: none"> ▪ Part 3 for new staff ▪ Part 4 for new test method ▪ Part 5 			
Other <input type="checkbox"/> <i>(Please specify)</i>					
Discipline for which Accreditation is sought <i>(Tick as appropriate)</i>					
Clinical Pathology	<input type="checkbox"/>	Hematology	<input type="checkbox"/>	Serology	<input type="checkbox"/>
Chemical Pathology	<input type="checkbox"/>	Microbiology	<input type="checkbox"/>	Histopathology	<input type="checkbox"/>
Immunology	<input type="checkbox"/>	Virology	<input type="checkbox"/>	Cytology	<input type="checkbox"/>
Radiology	<input type="checkbox"/>				
Other <i>(please specify)</i>					
ISO standard for which accreditation is sought					
ISO 15189		<input type="checkbox"/>	ISO/IEC 17025		<input type="checkbox"/>
Note: For Medical Laboratories whose scope of activity is solely medical, it is recommended that you apply for ISO 15189. If in any doubt please contact the SADCAS Technical Manager for clarification and advice.					
PART 2: INFORMATION REGARDING YOUR ORGANIZATION					
Description of the main activities of the applicant organization <i>(Please underline those activities for which accreditation is sought):</i> 					
<i>If the organization seeking accreditation is owned by another organization or is part of a larger organization or has branches/divisions at other locations, please give the following details:</i>					
Name, address and contact information (Tel, Fax, Email) of:					
Parent Organization					
Other organizations in group/ division					
Locations/sites/virtual sites where key activities are conducted					

Relationship and links between the above-mentioned organizations and the organization seeking accreditation <i>(Please describe)</i>			
What is the legal status of your organization? e.g. Pvt (Pty)/Ltd privately owned or other (List and attach the legal instrument and other regulatory requirements applicable to your organization)			
Registration Number of Company/ Identify Number(s) of sole owner or partners			
Total number of employees in the whole organization or group of organizations		Number of employees involved in area(s) seeking accreditation	
<i>Please attach an organogram of your organization indicating the structure of the sections/units/areas to be accredited and their relation to the rest of the organization.</i>			
Has the organization ever been accredited before? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes state name of accreditation body:			
Does the organization have an established formal management system? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If yes state standard upon which system is based:			
How long has this system been in operation?			
What training has been provided for the implementation and maintenance of the system			
To whom has the training been provided for?			
In which Proficiency Testing (PT) Schemes/Interlaboratory Comparisons do you or have you participated in? Note: Participation in PT schemes or interlaboratory comparisons is a prerequisite for accreditation.			
Scheme Name	Parameters	Frequency of Participation	



Scheme Name	Parameters	Frequency of Participation

PART 3: INFORMATION ON SENIOR STAFF

For each staff member having responsibility for a product or service for which accreditation is sought, please give the following details. This includes the Quality Manager and Technical Manager, where applicable.

Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			
Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			
Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			
Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			



Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			

Name		Position	
Area of responsibility		No. of staff supervised in area	
Qualifications, experience and training:			

PART 4: SCOPE OF APPLICATION

List all the test methods for which accreditation is sought.

Discipline	Materials Tested	Types of Tests Performed	Standard Method/ Technique Used	Description of Equipment Used



PART 5: DECLARATION	
Chief Executive Officer (CEO) or authorized official must authorize this form.	
The following is enclosed <i>(please tick as appropriate)</i>	
Copy of the Quality Manual	Application Fee: Transfer order placed <i>(please attach banking information on transfer)</i>
Other documentation SEE NOTE 1 <i>(Specify any attachment to the application form and/or tick below)</i>	
NOTE 1	
Documentation to be submitted prior to document review:	Tick
a) Duly completed Application Form	
b) Quality Management System Manual	
c) Completed SADCAS F 43 (f) Application for Approval of Personnel	
d) Information regarding active participation in PT schemes/Interlaboratory Comparisons	
e) Procedures/description of methods	
f) Procedure for validation of methods, an example of validation data	
g) Signed SADCAS Accreditation Agreement (SADCAS F 44)	
h) Proposed assessment dates (for scope extensions only)	
Note: Applications for scope extensions should be made six (6) weeks in advance prior to the scheduled assessment.	
<p>Upon accreditation, my organization commits to continually fulfil the the SADCAS accreditation requirements and procedures and any other obligations of the Laboratory</p> <p>I enclose a copy of the Quality Management System Manual and completed checklists.</p> <p>I enclose an application fee. I understand that this fee is not refundable.</p> <p>I understand the manner in which the accreditation system operates and its functions. SADCAS does not accept any responsibility for the actions, or the results of any actions, of an accredited organization. I, the undersigned, agree, as the authorized officer of the applicant independent entity that any liability of SADCAS which may arise due to negligence related to any accreditation is limited to a refund of the annual fee payable by the organization.</p> <p>I declare that the information given in this application is both correct and accurate to the best of my knowledge and belief. I undertake to inform SADCAS timeously of any changes with respect to the application and accept full responsibility for any costs incurred as a result of any changes not reported to SADCAS timeously.</p>	
Signed and stamped	
Name <i>(print)</i>	
Position	
Date	