APPLICATION FOR ACCREDITATION OF MEDICAL LABORATORIES	**FO7/1B**

For office use: EAS Acc.No	
Date of application	

The Medical Laboratory is applying for (Please tick in the appropriate box)

First Accreditation		Renewal of Accreditation		Pre-assessment		Scope Expansion	

1. THIS FORM SHOULD BE COMPLETED IN FULL AND RETURNED TO:

Ethiopian National Accreditation Office

Attention: Accreditation Director

PO Box 3898

ADDIS ABABA

Tel: +251 11 830 24 69/ +251 11 661 60 91

Fax: +251 11 618 41 54

E-mail: info@EAS-eth.org

Website:- www.EAS-eth.org

2. The Following documents shall be submitted together with the application form. **Types of documents: (Tick which is attached)**	**Yes**	**No**
► Quality Manual, Procedures and formats		
► PT participation plan and recent results		
► Procedure for method Verification/Validation and data		
► Major Equipments Calibration plan and Certificates		
► Completed Horizontal Check list form		
► Summary of Internal audit and clearance report.		
► Evidence about availability of adequate data after Implementation of Quality Management system (i.e. after conduct of internal Audit and NC clearance) as indicated in EAS P07 recent version.		
► For Calibration laboratories include BMC/CMC information		
► Risk Analysis Report		

3. LABORATORY DETAIL

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3.1. Name of the Laboratory									
Region		City							
Postal address									
Telephone:		Fax:							
E-mail:									
3.2. Name of Parent Organization (If part of an organization)									
Telephone:		Fax:							
E-mail:		Mobile (QMR)							
3.3. Legal Status and Date of Establishment (please give Registration No. and name of authority who granted the registration)									
3.4. The type of organization(Please tick the appropriate cage)									
Private limited Company		Private Partnership		Public limited company		Government body		Other	
3.5. Do you conduct Testing in the following Category (if yes, please clearly indicate in the scope of accreditation)									
a) Site Facility (when undertaking testing at site of the client)					Yes		No		
b) Temporary Facility (when a facility is created temporarily)					Yes		No		
c) Mobile Laboratory					Yes		No		
3.6. Details of primary sample collection facilities (please tick as appropriate and provide list of all facilities with complete contact details)									
At permanent facility (Lab. Prémisses)		At site (visit patient)		Other locations (collection centres)					
3.7. Testing Subcontracted (if yes, please specify the subcontracted work)			Yes			No			
3.8. Number of reports issued after conducting Internal audit and NC clearance.									

3.9. PT plan and List Proficiency Testing Schemes and frequency of participation in each scope the CAB intends to be accredited as per EAS accreditation process P07 clause 18.
3.10. Evidence of competence of Schemes and PT providers when applicable /available/
3.11. If alternatives of PT is used evidence for unavailability and impracticality for participation.
3.12. evidence for appropriateness of PT alternative as per EAS P07 clause 18.

4. ACCREDITATION DETAILS

4.1. Disciplines for which accreditation is sought

Clinical Chemistry		Virology		Mycology	
Bacteriology		Immunology		Cytology	

Parasitology		Serology		Histology	
Hematology		Molecular Biology		Urinalysis	
Endocrinology		Other (Please specify)			

4.2. Is your organization accredited by another accreditation body? If so please specify (attach documents for proof)

No.	Activity and Scope of Accreditation	Against which Standard/ Regulation	Name of Accrediting Institution	Period of Validity of Accreditation

4.3. Scope of Accreditation Sought

Please complete the following table as precisely as possible and include, wherever possible, standard methods and specification involved. This may be Ethiopian, regional and international standards. The title of the method or specification, its number and date of issue should be listed.

(use extra sheet if necessary)

No.	Materials/examined/ Tested	Specific tests/ examination performed	Major Equipment	Specification, standard (method) or technique used

4.4. Extension of Scope of Accreditation

If you wish to extend existing scope of accreditation, you will need to fill in this form and supply the following additional information:

I Accreditation Number	

II. Brief description of the scope of accreditation

III. Date of Expiry of accreditation	

IV. Extension Requested for and the applicable standard/regulation

5. ORGANIZATION

5.1. Authorized Representative for Accreditation related matters:	

5.1. Total number of Technical staff and signatories in medical testing laboratory for the specific field applied						
5.2. Please list the name and technical qualification of the following staff						
5.2.1. Technical manager (or equivalent) of medical testing laboratory body	Title		Full Name		Technical Qualification	
Deputy Technical Manager (or equivalent) of Medical Testing laboratory	Title		Full Name		Technical Qualification	
5.2.2. Quality Manager (or equivalent) of Medical Testing laboratory	Title		Full Name		Technical Qualification	

5.3. Person authorized to sign the test reports (please add separate sheet where required)

No	Test field	Name of authorized Person	Qualification	Work Experience (years)

5.4. Organization Chart (either annexed or cross referred to Quality Manual)

5.4.1. Indicate in an organization chart the operating departments of the medical testing laboratory for which accreditation is being sought (please append)

5.4.2. Indicate how the medical testing laboratory is related to external organizations or to its own parent organization (where applicable) (i.e. how its independence is ensured)

6. DECLARATION

I enclose a copy of the quality manual, a copy of the relevant, authorized test method(s) and the procedure for validation of methods.

I declare that I am authorized, on behalf of the company/ organization, to furnish this information, and the information contained herein is both correct and accurate to the best of my knowledge and belief.

Title	Position/Designation	Name	Signature	Date
	CEO/Manager/ G. Director			

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