

A. Information that is to be provided by the Medical Laboratory:

1. A written justification for the scope expansion.
2. Do any of the proposed modifications to the Scope require the laboratory to subcontract services or to lease test equipment?
 - a) If yes, please provide a list identifying the services and the equipment as appropriate.
3. Are outside consultants required in order to provide these new test services?
 - a) If yes, please provide a list of these consultants and which services they provide.
 - b) Also, please indicate if these consultants were available and present at the last A2LA assessment?
4. Please provide a copy of the Procedure for each proposed Scope addition or modification.
5. Please complete the following table for each requested modification to the Scope of Accreditation.
6. Please provide all testing validation, reliability, and accuracy studies demonstrating that the proposed additional testing is functioned as designed.


Test Technology	Proposed Method or Rev on A2LA Scope	*Identify Trained Staff	**Added Equipment	Test Procedure	Actual or Sample Test Report

*Please include evidence of applicable staff training for the test method(s) requested to be added.

**Please include evidence of traceable calibration for the equipment indicated.

Please note that additional information may be requested to perform the review of the methods for which the scope expansion has been requested.

B. Assessor Review of provided data

	<i>The American Association for Laboratory Accreditation</i>	
	F609 –Request for Expansion of Scope of Accreditation – Medical Testing	Document Issued: February 26, 2010 Page 2 of 2

1. After this information has been provided to A2LA, it will be forwarded to the medical assessor(s) that last visited your laboratory. These subject matter experts will be requested to perform a technical review on the information.

2. Based on the initial review by the assessor, one or more of the following options will be communicated to the laboratory:
 - a) A desk audit and document/information review (a teleconference may be necessary) is performed either by an A2LA assessor or A2LA staff, as appropriate;
 - b) The result of the desk audit and document review may be that an on-site assessment visit is required.
 - c) An interim on-site assessment by an A2LA Medical Assessor.
 - d) Tentative scope approval based on the review of the information that has been already provided.

If you have any questions please contact your MAcO for further information.