



LAS-A012

ASSESSOR CHECKLIST: GENERAL CRITERIA (ISO 15189)

Issued by: TTLABS
Approved : Manager, TTLABS
Revision Date: January 2007

ASSESSOR CHECKLIST: GENERAL CRITERIA (ISO 15189)

(Includes the TTLABS Advertising Policy and the TTLABS Measurement Traceability Policy requirements)

The following pages present a **summary** of the criteria from ISO 15189-2003, which is the basis for the TTLABS General Requirements for Accreditation of Medical Laboratories in a checklist format. **The laboratory's policies and procedures must meet the full requirements of ISO 15189. Laboratories and assessors must refer to the actual standard for the definitive language of the requirements.**

If the ISO 15189 requirements include the need for a written policy, procedure or arrangement, that requirement statement in this checklist is shaded. Quality system documentation and supporting records must be available for the assessor's review.

The laboratory must complete the document reference identifiers in the checklist's second column (labeled "Reference"), place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item and submit this checklist as part of the application for accreditation. This serves to help both the laboratory and the assessors prepare for the assessment and may save a significant amount of assessment time and cost. The appropriate "reference" must identify the document (quality manual, laboratory manual, SOPs, records, etc.), and include a 'locator' to facilitate identification of the appropriate portion(s) of the relevant document. This 'locator' may be in the form of a page number, section number, etc.

Additional requirements from the TTLABS Advertising Policy and the TTLABS Policy on Measurement Traceability are included at the end of this checklist.

Assessor Instructions: Review the laboratory's documented quality system to verify compliance with the applicable 15189 documentation requirements. Assess to verify that the documented quality system is indeed implemented as described. Record comments related to any requirement on the space provided. Assess the laboratory's technical competence to perform specific tests. Record comments related to tests on separate sheets and/or on the test method review matrix. All deficiencies must be identified and explained in the assessor deficiency report.

Laboratory Name: _____

Address: _____

Personnel Information (Names, Titles, and Responsibilities):

Technical Management: _____

Quality Manager: _____

Deputy QM: _____

Assessor:

**TTLABS General Requirements for Accreditation of Medical Laboratories
Checklist**

To the best of my knowledge, all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of the TTLABS General Requirements for Accreditation of Medical Laboratories. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

TTLABS Assessor Signature: _____ Date: _____

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4. MANAGEMENT REQUIREMENTS					
4.1 Organization					
4.1.1 Legally identifiable					
4.1.2 Medical laboratory services (including appropriate interpretations and advisory services) shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.					
4.1.3 Requirements of ISO 15189 shall be met when carrying out work at its permanent facilities or at other sites for which it is responsible.					
4.1.4 Responsibilities of personnel					
4.1.5 Laboratory requirements					
a) Management support of all laboratory personnel					
b) Undue internal and external pressures					
c) Confidential information					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
d) Policies and procedures to avoid involvement in inappropriate activities					
e) Organization and management structure					
f) Responsibility, authority and interrelationships of personnel					
g) Adequate and appropriate training and supervision of all staff by competent persons					
h) Technical management					
i) Quality manager					
QM access to the highest level of management					
j) Deputies					
4.2 Quality management system					
4.2.1	Appropriate quality management system				
	Documented policies, processes, programs, procedures and instructions				
	Documentation communicated, understood and implemented				
4.2.2	The Quality Management system shall at least include:				
a)	Internal Quality Control				
b)	Participation in organized inter-laboratory comparisons (external quality assessment schemes)				

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.2.3 Policies and Objectives					
Quality Policy Statement shall be:					
a) Issued under the authority of the Laboratory Director.					
b) Documented in a Quality Manual					
c) Readily available to appropriate personnel					
d) Concise					
Quality Policy Statement shall include:					
a) Scope of laboratory's services					
b) Laboratory management's statement of its standard of service					
c) The objectives of the Quality Management System					
d) Requirements that relevant personnel familiarize themselves with quality documentation and implement policies and procedures at all times					
e) Laboratory's commitment to good professional practice, quality of examinations and compliance with quality management system					
f) Laboratory management's commitment to compliance with ISO 15189					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.2.4 Quality Manual describing the quality management system and the structure used in the quality management system					
Quality Manual shall include or make reference to:					
a) Supporting procedures (including technical procedures)					
b) Outline the structure of the documentation in the Quality Management System.					
c) The roles and responsibilities of the technical and quality manager.					
d) Responsibility of Quality Manager and Technical Manager to ensure compliance with ISO 15189					
e) All personnel shall be instructed on the use and application of the quality manual and all referenced documents and of the requirements for their implementation.					
f) The person responsible for quality shall ensure that the quality manual is kept up to date.					
4.2.5 A proper calibration program shall be established and implemented.					
Preventive maintenance program that is documented and recorded.					
4.3 Document control					
4.3.1 Procedures to control all quality system documents					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>Archive copies of control documents with Laboratory Director authorizing the Retention Period.</p> <p>a) Reviewed and approved by authorized personnel</p> <p>b) Document control log or list</p> <p>c) Current authorized versions</p> <p>d) Periodic review</p> <p>e) Invalid or obsolete documents removal</p> <p>f) Retained/Archived superseded documents identified</p> <p>g) Document changes/amendments defined Amendments clearly marked, initialed and dated, and a revised document formally re-issued as soon as possible.</p> <p>h) Changes to documents in computerized systems</p>					
<p>4.3.3 All documents uniquely identified to include</p> <p>a) Title</p> <p>b) Edition or current revision date, or number, or all these</p> <p>c) number of pages</p> <p>e) authority for issue</p> <p>f) source identification</p>					
4.4 Review of Contracts					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.4.1 Procedures for review of contracts					
Policies and procedures leading to a change in arrangements of contracts shall ensure that:					
a) requirements, including methods to be used, are adequately defined, documented and understood.					
b) the lab has capability and resources					
c) procedures are able to meet contract requirements and clinical needs					
4.4.2 Records of reviews					
4.4.3 Review of referred work					
4.4.4 Deviations from contract					
4.4.5 Amendment after work has commenced					
4.5 Examination by referral laboratories					
4.5.1 Effective documented procedure for evaluating and selecting referral laboratories. Laboratory management shall be responsible (where appropriate) for selecting and monitoring the quality and competence of referral and consultants.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>4.5.2 Arrangements with referral laboratories shall be reviewed to ensure that:</p> <p>a) Pre-examination & post – examination procedures are adequately defined, documented and understood.</p> <p>b) They can meet the requirements and there is no conflict of interest</p> <p>c) Selection of examination procedures are appropriate for intended use</p> <p>d) Responsibilities for the interpretation of the examination results are clearly defined</p> <p>Records of such reviews shall be maintained in accordance with national, regional or local requirements</p>					
<p>4.5.3 Laboratory shall maintain a register of all referral laboratories. The name and address of all laboratories responsible for examination results shall be provided to the user of laboratory services.</p> <p>A duplicate of the laboratory results shall be retained in both patient records and permanent file.</p>					
<p>4.5.4 The referring laboratory shall be responsible providing the examination results to the person making the request.</p>					
<p>4.6 External services and supplies</p>					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.6.1 Documented policies and procedures for the selection and use of external services, equipment and consumable supplies. Purchased items shall consistently meet the lab's quality requirements.					
4.6.2 Purchased equipment and consumable supplies shall only be used if verified as complying with standard specifications or requirements for the procedure.					
Verification can be accomplished by examination of quality control samples or documentation of supplier's conformance with its quality system.					
4.6.3 Inventory control system for supplies.					
4.6.3 Appropriate quality records of external services, supplies and purchased products shall be established. Quality records shall be available for management review.					
4.6.4 Evaluation of suppliers of critical reagents, supplies and services.					
4.7 Advisory Services					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>Appropriate laboratory professional staff shall give advice on the use of services and choice of examinations. Interpretation of the results shall be provided, where appropriate.</p> <p>Meetings of professional staff and clinical staff regarding the use of services and consultation on scientific matters shall be regular.</p>					
4.8 Resolution of Complaints					
Policy and procedure for resolution of complaints					
Records of complaints, investigations and corrective actions					
4.9 Identification and control of nonconformities					
4.9.1 Policy and procedure for implementation when its examination does not conform with its own procedures or the requirements its quality system or the requesting clinician. These shall ensure:					
a) Personnel responsible for resolving the problem are designated.					
b) The actions to be taken are defined.					
c) The medical significance of nonconforming examinations is considered and where appropriate the medical clinician is informed.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
d) Examinations are halted and reports withheld as necessary.					
e) Corrective action is taken					
f) The results of nonconforming examinations are recalled or identified if already released.					
g) the responsibility for the authorization of the resumption of examinations are defined, if necessary.					
h) Each episode of nonconformity is recorded, with these records being reviewed at regular intervals by laboratory management to detect trends and initiate preventive action.					
4.9.2 Procedures to identify, document and eliminate the root cause of recurring nonconforming examinations shall be promptly implemented (see 4.11)					
4.9.3 Define and implement procedures for the release of results in the case of nonconformities, including review of such results. These events shall be recorded.					
4.10 Corrective action					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.10.1 Procedure for corrective action shall: a) Include an investigative process to determine cause of the problem. b) Lead to, where appropriate, preventive actions. c) Be appropriate to the magnitude of the problem and equal to the risks encountered.					
4.10.2 Changes required to the operational procedures due to corrective action investigations shall be documented and implemented.					
4.10.3 Results of corrective actions taken shall be monitored to ensure effectiveness in resolving the problem.					
4.10.4 Appropriate areas of activities shall be audited in accordance with 4.14, when identification of nonconformance or corrective action investigation casts doubt on compliance with quality management system or the policy and procedures.					
4.11 Preventive action					
4.11.1 Identification of improvements and potential sources of nonconformances					
Action plans shall be developed, implemented and monitored.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.11.2 Procedures for preventive action: a) Shall include effective actions and application of controls b) May involve analysis of data, including trend – and risk- analyses and external quality assurance.					
4.12 Continual Improvement					
4.12.1 Operational system shall be reviewed to identify potential sources of nonconformities or opportunities for improvement Action plans for improvement shall be developed, documented and implemented.					
4.12.2 Actions taken from review shall be evaluated for its effectiveness via focused review or audits					
4.12.3 Results of actions taken shall be submitted for review and implementation of any needed changes to the quality system, by laboratory management					
4.12.4 Quality indicators shall be implemented for systematically monitoring and evaluating the lab’s contribution to patient care.					
4.12.5 Access to suitable education and training shall be provided.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]	
	Y	N	NA			
4.13 Quality and Technical Records						
4.13.1	Establish and implement procedures for identification, collecting, indexing, access, storage, maintenance and safe disposal of quality and technical records					
4.13.2	Records shall be legible and retrievable					
	Storage facilities shall prevent damage, deterioration, loss or unauthorized access to records					
4.13.3	Policy that defines retention times for records pertaining to the quality management system and examination results.					
	Retention times shall be defined by the nature of the examination or specifically for each record.					
4.14 Internal audits						
4.14.1	Internal audits of both managerial and technical elements of the system shall be carried out at defined intervals Audits shall emphasize areas critically important to patient care.					
4.14.2	Audits shall be formally planned, organized and carried out by the Quality Manager or designate.					
	Main elements of the quality system shall be audited once every 12 months.					
	Procedures for internal audits shall be defined and documented					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
Procedures shall include: a) Types of audit b) Frequencies c) Methodologies d) Required documentation					
Appropriate corrective or preventive actions shall be documented and undertaken within an agreed time frame.					
4.14.3 Internal audit results shall be submitted to management for review.					
4.15 Management review					
4.15.1 Review the quality management system and all its medical services (including examination and advisory services)					
Results of the review shall be included into a plan that includes goals, objectives and action plans.					
A typical period for conducting a management review is once every 12 months					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>4.15.2 Management review shall take account of :</p> <ul style="list-style-type: none"> a) Follow up of previous management review b) status of corrective action taken and required preventive actions c) reports from managerial and supervisory personnel d) outcome of recent internal audits e) assessment by external bodies f) the outcome of external quality assessment and other forms of interlaboratory comparison g) changes in the volume and type of work h) feedback from clinicians, patients and other parties i) quality indicators for monitoring the laboratory's contribution to patient care j) nonconformities k) monitoring of turnaround time l) results of continuous improvement processes, and m) evaluation of suppliers 					
<p>4.15.3 Monitor and evaluate the quality and appropriateness of laboratory's contribution to patient care.</p>					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.15.4 Management review findings and the actions taken from review shall be recorded					
Arising actions shall be discharged within an appropriate and agreed timeframe.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5 TECHNICAL REQUIREMENTS					
5.1 Personnel					
5.1.1 Qualifications and duties shall be defined in: a) an organizational plan b) personnel policies c) job descriptions					
5.1.2 Maintain records of : a) educational and professional qualifications b) training c) experience d) and competence of personnel					
5.1.3 The laboratory shall be directed by a person who has executive responsibility and competence to assume responsibility for the services provided					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.1.4 Responsibilities of the Laboratory Director shall include: <ul style="list-style-type: none"> a) professional b) scientific c) consultative/advisory d) organizational e) administrative f) and, educational matters These shall be relevant to the services offered by the laboratory.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>5.1.4 The laboratory Director or Designees shall have the appropriate training and background to be able to discharge the following responsibilities:</p> <ul style="list-style-type: none"> a) Provide advice about the choice of test, the use of the lab service and the interpretation of data. b) Serve as active members of the medical staff for those facilities served. c) Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the health care community and the patient population served. d) Define, monitor and implement standards or performance and quality improvement in medical lab services. e) Implement the quality management system f) Monitor work performed in the lab to determine reliability of data generated. g) Qualified personnel with documented training and experience to meet the needs of the lab. h) Plan, set goals, develop and allocate resources appropriate to the medical environment. 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
i) Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management					
j) Provide educational programs for medical and laboratory staff and participate in educational programs					
k) Plan and direct research and development appropriate to the facility.					
l) Select and monitor all referral labs for quality of service					
m) Implement a safe lab environment in compliance with good practice and applicable regulations					
n) Address any complaint, request or suggestion from users of laboratory services					
o) Ensure good staff morale The laboratory director has overall responsibility for administration and operations of the laboratory, for ensuring that quality services are provided for patients.					
5.1.5 Resources shall be adequate for carrying out the functions of the quality management system					
5.1.6 Quality assurance and quality management training for personnel					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.1.7 Authorized personnel shall perform particular tasks					
5.1.8 Define policies for: a) use of the computer system b) who may access patient data c) authorization to enter and change patient results, correct billing or modify computer programs					
5.1.9 Continuing education program available to staff at all levels					
5.1.10 Train employees in containment and prevention of adverse incidents					
5.1.11 Assessment of the competence of each person to perform assigned tasks following training. Retraining and reassessment shall occur where necessary					
5.1.12 Personnel responsible for making professional judgment (with reference to examination) shall have applicable theoretical and practical experience. Professional judgment shall be in accordance with national, regional and local regulations					
5.1.13 Personnel shall participate in professional development or professional liaison.					
5.2 Accommodation and environmental conditions					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.2.1 Allocated space to facilitate workload that would not compromise quality of work, quality control procedures, safety of personnel or patient care services.					
The laboratory Director shall determine the adequacy of the space for performance of work.					
Laboratory resources shall be able to support the activities of the laboratory.					
Laboratory resources shall be maintained in a functional and reliable condition.					
Primary sample collection and examinations at other sites shall have similar provisions as obtained for permanent facilities					
5.2.2 The laboratory shall be designed: <ul style="list-style-type: none"> a) for efficiency of operations b) to optimize occupants comfort c) to minimize risk of occupational injuries and illnesses d) to protect patients, employees and visitors from recognized hazards 					
5.2.3 Primary sample collection facilities shall give consideration to accommodation of patient disability, comfort and privacy, in addition to the optimization of collection conditions					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.2.4 The laboratory design and environment shall be suitable and shall not invalidate the results, or adversely affect required quality, of any measurement.					
5.2.4 Facilities shall allow correct performance of examinations. These include: a) energy sources b) lighting c) ventilation d) water e) waste f) refuse disposal and g) environmental conditions					
5.2.4 Procedures for checking that environmental conditions does not adversely affect the performance of specimen collection and equipment					
5.2.5 Monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.2.5 Attention shall be paid to: a) sterility b) dust c) electromagnetism interference d) radiation e) humidity f) electrical supply g) temperature h) sound and vibration levels As appropriate to the technical activity concerned.					
5.2.6 Effective separation between adjacent incompatible laboratory sections. Measures shall be taken to prevent cross contamination					
5.2.7 Control of access to and use of areas affecting quality of the examinations					
5.2.8 Communication systems shall be appropriate to the size and complexity of the facility and efficient transfer of the message					
5.2.9 Provision of relevant storage space and conditions to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, document files, manuals, equipment, reagents, laboratory supplies, records and results					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.2.10 Clean and well maintained work areas. Good house keeping shall be taken					
Storage and disposal of dangerous material shall be specified by relevant regulations.					
5.3 Laboratory Equipment					
5.3.1 Furnish laboratory with equipment required for the provision of services					
Use of equipment outside the labs permanent control shall meet the requirements of ISO/IEC 15189					
Equipment selection shall take into account energy use and future disposal					
5.3.2 Equipment shall be capable of achieving performance criteria and shall comply with the specifications of the relevant examinations					
Program for monitoring proper calibration and function of instruments, reagents and analytical systems.					
Documented and recorded program of preventive maintenance					
Manufacturer's instructions, operator's manuals or other documentation may be used to establish requirements, for compliance with relevant standards or to specify requirements for periodic calibration, as appropriate, to fulfill part or all of this requirement					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.3.3 Unique marking / labeling or identification of equipment.					
5.3.4 Records of each item of equipment contributing to the performance of examinations shall be maintained and shall include: <ul style="list-style-type: none"> a) identity of the equipment b) manufacturer's name, type identification and serial number or other unique identification c) manufacturer's contact person and telephone number, as appropriate d) date of receiving and date of putting into service e) current location, where appropriate; f) conditions when received (e.g. new, used or reconditioned); g) manufacturer's instructions, if available, or reference to their retention; h) equipment performance records that confirm the equipment's suitability for use; i) maintenance carried out and that planned for the future j) damage to, or malfunction, modification or repair, of the equipment; k) predicted replacement date 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.3.4 These records shall be maintained and (cont'd) remain available for the life of the equipment or for any time period required by law.					
5.3.5 Only authorized personnel shall operate equipment.					
Lab personnel shall have available up-to-date instructions on the use and maintenance of equipment.					
5.3.6 Maintain equipment in safe working condition. This shall include: a) examination of electrical safety b) emergency stop devices c) safe handling and disposal of chemical, radioactive and biological material by authorized persons. d) Use manufacturer's specifications or instructions or both shall be used in maintaining safe working equipment.					
5.3.7 Defective equipment shall be taken out of service, clearly labeled and appropriately stored					
Only when defective equipment have been repaired and shown by calibration, verification and testing to meet specified acceptance criteria can they be brought back into service.					
Examination of the effect of defective equipment on previous examinations and institute the procedure 4.9.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
Decontaminate equipment prior to service, repair or decommissioning					
5.3.8 Provide a list of measures taken to reduce contamination to the person working on the equipment					
Provide suitable space for repairs and appropriate personal protective equipment.					
5.3.9 Equipment requiring calibration shall be labeled or otherwise coded, indicating their status of calibration or verification and the date when recalibration or re-verification is due					
5.3.10 Repaired or serviced equipment shall be checked and shown to be satisfactorily functioning before returning to lab use					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>5.3.11 The laboratory shall ensure that computers and automated equipment used for collecting, processing, recording, reporting, storage or retrieval of examination data shall ensure that:</p> <p>a) Computer software, is documented and suitably validated as adequate for use in the facility</p> <p>b) Procedures are established and implemented for protecting the integrity of data at all times</p> <p>c) Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and</p> <p>d) Computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons</p>					
5.3.12 Procedures for safe handling, transport, storage and use of equipment, to prevent its contamination or deterioration					
5.3.13 Procedures that ensure copies of prior correction factors are correctly updated					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.3.14 Equipment shall be safeguarded from adjustments or tampering that might invalidate examination results					
5.4 Pre-examination procedures					
5.4.1 The request form shall: a) identify the patient and authorized requester b) provide pertinent clinical data The request form or an electronic equivalent should allow for the inclusion of, but not limited to, the following: a) unique identification of the patient; b) name or other unique identifier of physician or other person legally authorized to request examinations or use medical information together with the destination for the report; the requesting clinician's address c) type of primary sample and the anatomic site of origin, where appropriate; d) examination requested; e) clinical information relevant to patient, which should include gender and date of birth, as a minimum f) date and time of primary sample collection; g) date and time of receipt of samples by the laboratory					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
The format of the request form and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services.					
5.4.2 Documentation of instructions for the proper collection and handling of primary samples shall be implemented					
Instructions shall be contained in a primary sample collection manual					
5.4.3 The primary sample collection manual shall include: a) copies of references to (1) list of available laboratory examinations offered (2) consent forms when applicable (3) information and instructions provided to patients in relation to their own preparation before primary sample collection, and (4) information for users of laboratory services on medical indication and appropriate selection of available procedures					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.4.3 (cont'd) b)procedures for (1) preparation of patient (2) identification of primary sample (3) primary sample collection c)instructions for (1) completion of request form or electronic request (2) type and amount of primary sample to be collected (3) special timing of collection, if required, (4) any special handling needs between time of collection and time received by the laboratory (5) labeling of primary samples (6) clinical information (7) positive identification (8) recording the identity of persons collecting the primary sample (9) safe disposal of material used in collection d)instructions for (1) storage of examined samples (2) time limits for requesting additional examinations					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
(3) additional examinations, and (4) repeat examination due to analytical failure or further examinations of same primary sample					
5.4.4 The primary collection manual shall be part of the document control system					
5.4.5 Primary sample shall not be accepted if not properly identified or traceable by the request form to an identified individual					
5.4.6 The laboratory shall monitor the transportation of samples to the laboratory					
5.4.7 Primary samples to be recorded in an accession book, worksheet, computer or other comparable system					
Record date and time of sample receipt and the identity of the receiving officer					
Develop and document criteria for acceptance and rejection of primary samples					
Final report shall indicate that compromised primary samples were accepted, together with the nature of the problem and that caution is required when interpreting the results.					
5.4.9 Periodically review sample volume requirements for phlebotomy ensuring neither insufficient nor excessive amounts of sample are collected.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.4.10 Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the method to be used					
5.4.11 Have a documented procedure for receipt, labeling, processing and reporting of primary samples marked as urgent					
<p>The procedure shall include:</p> <ul style="list-style-type: none"> a) details of any special labeling of the request form and primary sample b) the mechanism of transfer of the primary sample to the examination area of the laboratory c) any rapid processing mode to be used d) any special reporting criteria to be followed 					
5.4.12 Sample portion shall be traceable to the primary sample					
5.4.13 Written policy concerning verbal requests for examinations					
<p>5.4.14 Sample storage shall be:</p> <ul style="list-style-type: none"> a) For a specific time b) Under conditions ensuring stability of sample properties c) such that it enables repetition of the examination after reporting of the result or for additional examinations 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.5 Examination Procedures					
5.5.1 Use examination procedures that meet the needs of the users of the laboratory services and are appropriate for the examinations					
Use of in-house procedures must be validated for their intended use					
5.5.2 Only validated procedures shall be used for confirming that examination procedures are suitable for its intended use.					
Laboratory shall record the results obtained and the procedure used for the validation					
Methods and procedures selected for use before being placed into service					
5.5.3 All procedures shall be documented (in a language understood by laboratory staff) and be available at the workstation for relevant staff.					
Card files used shall correspond to the complete manual and the manual shall be made available for reference.					
Any such abridged procedures shall be part of a document control system.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
Procedures shall be based on the instruction for use written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure as is performed in the laboratory and are written in the language commonly understood by the staff of the laboratory.					
Deviations from procedures shall be reviewed and documented					
Additional information required to perform examinations shall also be documented.					
Each new version of examination kits with major changes in reagents or procedures shall be checked for performance and suitability for intended use.					
Any procedural changes shall be dated and authorized as for other procedures.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>Documentation should include, when applicable, the following:</p> <ul style="list-style-type: none"> a) purpose of examination b) principles of the procedures used for examinations c) performance specifications d) primary sample system e) type of container and additives f) required equipment and reagents g) calibration procedures h) procedural steps i) quality control procedures j) interferences k) principles of procedure for calculating results, including measurement uncertainty. l) Biological reference intervals m) Reportable intervals of examination results n) Alert/critical values where appropriate o) Laboratory interpretation p) Safety precaution q) Potential sources of variability 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
Electronic manuals are acceptable provided the above specified information is included. The same requirement for document control should apply to electronic manuals.					
The laboratory director shall be responsible for ensuring that the contents of examination procedures are complete and have been thoroughly reviewed.					
5.5.4 Performance specification for each procedure used in an examination shall relate to the intended use.					
5.5.5 Biological reference intervals shall be periodically reviewed.					
A review of biological reference intervals shall take place when there is reason to believe that a particular interval is no longer appropriate for the reference population or when the laboratory changes an examination procedure or pre-procedure.					
5.5.6 The laboratory shall make its list of current examination procedures available to users of laboratory services upon request.					
5.5.7 If results or their interpretations could be significantly different if the laboratory intends to change its examination procedures, the implications shall be explained to users of the laboratory services in writing					
5.6 Assuring quality of examination procedures					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.6.1 Design internal quality control systems that verify the attainment of the intended quality of results.					
Control systems should provide staff with clear and easily understood information on which to base technical and medical decisions.					
Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examination, reports, etc.					
5.6.2 Uncertainty of the results shall be determined where possible					
Important uncertainty components shall be taken into account					
5.6.3 Design a program for calibration of measuring systems and verification of trueness., so as to ensure results are traceable to SI Units or by reference to a natural constant or other stated reference					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>Where these are not possible or relevant, confidence in the results obtained shall be applied by other means, including but not limited to:</p> <ul style="list-style-type: none"> a) participation in a suitable program of inter-laboratory comparisons b) use of suitable reference material, certified to indicate the characterization of the material c) examination or calibration by another procedure d) ratio of reciprocity – type measurements e) mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned. f) Documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer. 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
<p>5.6.4 The laboratory shall participate in inter-laboratory comparisons.</p> <p>Monitor the results of external quality assessment and participate in the implementation of corrective actions when criteria are not fulfilled.</p> <p>Inter-laboratory comparison programs shall be in substantial agreement with ISO/IEC Guide 43-1</p>					
<p>5.6.5 The laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated, when a formal inter-laboratory comparison program is not available.</p>					
<p>- The developed mechanism shall utilize externally derived challenged material such as exchange of samples with other laboratories.</p>					
<p>Laboratory management shall monitor the results of this mechanism of inter-laboratory comparison</p>					
<p>5.6.6 A mechanism for verifying comparability of results shall be defined for examinations performed using different procedures or equipment or at different sites.</p>					
<p>5.6.7 Document, record and expeditiously act upon results from these comparisons.</p> <p>Problems or deficiencies identified shall be acted upon and recorded actions retained.</p>					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.7 Post-examination procedures					
5.7.1 Results of examinations reviewed and evaluated by authorized personnel					
5.7.2 Primary sample and other lab samples shall be stored in accordance with approved policy.					
5.7.3 Samples safely disposed in accordance with local regulations or recommendations for waste management					
5.8 Reporting of results					
5.8.1 Laboratory management responsible for formatting reports. Format of report form and manner to be communicated should be determined with users of lab services.					
5.8.2 Responsibility of laboratory management and requester to ensure reports are received by appropriate individuals within agreed-upon time interval					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.8.3 Results shall be: <ul style="list-style-type: none"> (a) Legible (b) Without mistakes in transcription (c) Reported to persons authorized to receive and use medical information and include: <ul style="list-style-type: none"> (a) Clear, unambiguous identification of the examination (b) Identification of laboratory issuing report (c) Unique identification and location of patient (d) Name/unique identifier of requester and requester's address (e) Date and time of primary sample collection (f) Date and time of release of report (g) Source or system (h) Results reported in SI units or units traceable to SI units (i) Biological reference intervals (j) Interpretation of results (k) Other comments (l) Identification of person authorizing release of report (m) Original and corrected results if relevant (n) Signature or authorization of person checking or releasing report 					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.8.4 Description of examinations and results should follow vocabulary and syntax of recommended organizations Description and results should follow nomenclature of recommended organizations					
5.8.5 Report shall indicate if quality of primary sample received was unsuitable or could have compromised the result					
5.8.6 Copies or files of reported results shall be retained so prompt retrieval of information is possible					
5.8.7 Procedures for immediate notification of physician when results fall within “alert” or “critical” intervals					
5.8.8 The laboratory and clinicians shall determine critical properties in order that local clinical needs are served					
Applies to all examinations both nominal and ordinal properties					
5.8.9 Final report shall always be forwarded to requester for results transmitted as an interim report					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.8.10 Records of actions taken in response to critical results shall be maintained. These include: (a) Date (b) Time (c) Responsible laboratory staff member (d) Person notified (e) Examination results					
5.8.11 Lab management and requesters shall establish turnaround times for each examination.					
Policy for notifying requester when examination is delayed.					
Turnaround times shall be monitored, recorded and reviewed by laboratory management					
5.8.12 Procedures for verifying correctness of all transcriptions when examination results from a referral laboratory need to be transcribed by the referring laboratory.					
5.8.13 Clearly documented procedures for release of examination results					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
5.8.14 Establish policies and practices for ensuring results distributed by telephone/electronic means reach only authorized receivers.					
5.8.15 Written policies and procedures regarding alteration of reports					
Altered reports must show time, date and name of person responsible for change					
Original entries remain legible when alterations are made					
Original electronic records retained					
5.8.15 Results available for clinical decision-making and revised shall be retained in subsequent cumulative reports and clearly identified. Audit log used if reporting system cannot capture amendments, changes or alterations.					

LABORATORY REFERENCE TO TTLABS ACCREDITED STATUS – TTLABS ADVERTISING POLICY
(ADDENDUM TO THE ASSESSOR CHECKLIST: GENERAL CRITERIA)

(Effective April 30, 2004)

TTLABS-accredited laboratories are strongly encouraged to promote their TTLABS accreditation by using the “TTLABS Accredited” symbol.

It is the ethical responsibility of accredited and applicant laboratories to describe their accredited status in a manner that does not imply accreditation in areas that are outside their actual scope of accreditation or for other testing/calibration facilities not covered under TTLABS accreditation. Accredited laboratories or others are encouraged to advise TTLABS if a violation of this policy is discovered by actions of other parties.

While inclusion of the TTLABS symbol on test or calibration reports is not mandatory, only test or calibration reports bearing the TTLABS symbol can benefit from the acceptance established through mutual recognition agreements/arrangements among accreditation bodies, and only those calibration reports bearing the TTLABS symbol can be confirmed to meet the TTLABS Traceability Policy.

Unless otherwise specified, all requirements related to the use of the “TTLABS Accredited” symbol specified in this document also apply when making any other claims of TTLABS accreditation. The term "certificates and reports" includes calibration certificates and test reports.

Failure to comply with these requirements may lead to denial, suspension or revocation of accreditation and/or legal remedies.

(Note: Laboratories initially applying for TTLABS accreditation should indicate "NA" for all items on this checklist addendum for describing the accredited status but must sign the statement on the last page agreeing to abide by this advertising policy once accredited.)

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
1.0 General Requirements					
1.1 The laboratory shall have a policy and procedure for controlling the use of the term “TTLABS” and the “TTLABS Accredited” symbol.					
1.2 The “TTLABS Accredited” symbol shall not be used by a laboratory that is not TTLABS accredited.					
1.3 The “TTLABS Accredited” symbol shall not be used by applicants for TTLABS accreditation.					
1.4 The “TTLABS Accredited” symbol shall be used by a TTLABS accredited laboratory only under the name in which it holds TTLABS accreditation.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
1.5 When promoting or providing proof of accreditation, accredited laboratories shall use the scope(s) of accreditation, as this document details the specific tests or calibrations which are accredited. The certificate shall be used for display purposes and may also accompany the scope.					
1.6 It is the responsibility of the laboratory to communicate this Advertising Policy and its requirements to the necessary corporate/marketing representatives to ensure that all requirements are met.					
2.0 Symbol Reproduction					
2.1 "TTLABS Accredited" symbol sheets are sent to all accredited laboratories, and an electronic version is available upon request.					
2.2 Where the TTLABS name and/or symbol are used by accredited laboratories, it shall always be accompanied by at least the word "accredited."					
2.3 While there are no restrictions on the size and color of the "TTLABS Accredited" symbol reproduction, the symbol must maintain its form.					
2.4 The "TTLABS Accredited" symbol may be generated electronically provided that the prescribed formats and forms are retained.					
3.0 Use of the "TTLABS Accredited" symbol on Test/Calibration Reports					
3.1 Where the "TTLABS Accredited" symbol is used to endorse test or calibration results, it shall always be accompanied by the TTLABS certificate number(s).					
3.2 The "TTLABS Accredited" symbol may be displayed on all certificates and reports that contain exclusively results from calibrations and tests that have been carried out within the laboratory's official TTLABS Scope of Accreditation.					
3.3 The "TTLABS Accredited" symbol shall not be used on certificates and reports if none of the results presented are from tests or calibrations included on the TTLABS Scope(s) of Accreditation.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
3.4 Where both accredited and non-accredited tests/calibrations are included on an endorsed report or certificate, non-accredited results shall be clearly and unambiguously identified as such. This can be done by placing an asterisk after each such result along with a footnote stating: <i>“The test/calibration results are not covered by our current TTLABS accreditation”</i> .					
3.5 On reports where results are reported within the field where accreditation exists but in a technology that is not included in the scope, they must be so indicated. (For example, if a laboratory is accredited in the Environmental Field for only wet chemistry and metals, any gas chromatographic data reported would need to be identified as non-accredited.)					
3.6 If the intent is to ensure that the client meets the requirements of the TTLABS Traceability Policy, the calibrations performed by a TTLABS accredited calibration laboratory must be included on the calibration laboratory's TTLABS Scope of Accreditation and the calibration certificate issued must contain the “TTLABS Accredited” symbol and the TTLABS certificate number.					
3.7 There shall be nothing in the reports, certificates or in any attachments or other materials which implies or may lead any user of the results or any interested party to believe that the work is accredited when it is not.					
4.0 Subcontracted Tests and Calibrations					
4.1 A TTLABS accredited laboratory may include the results of subcontracted tests or calibrations in its endorsed reports or certificates only if:					
4.1.1 The accredited laboratory has informed the client in writing of the proposed subcontracting and has obtained prior approval; and					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
4.1.2 The subcontractor is itself accredited by TTLABS or a TTLABS recognized MRA partner for the specific tests or calibrations concerned and the results have been included in the subcontracting laboratory's endorsed calibration or test report(s) submitted to the accredited laboratory. Any non-accredited subcontracted calibrations or tests shall be specified as noted in Section 3.4 of this policy.					
4.1.3 The subcontracted calibration or test results shall be clearly and unambiguously identified on the certificate or report.					
5.0 Opinions and Interpretations					
5.1 Where statements of opinions and interpretations are outside the Scope of Accreditation, the laboratory is required to include a disclaimer such as the following in the certificate or report: <i>“The opinions/interpretations expressed in this report are outside the scope of this laboratory's TTLABS accreditation.”</i>					
5.2 It is preferable, however, to express opinions and interpretations that are outside the Scope of Accreditation on a separate letter which is not part of the endorsed certificate or report and that does not carry the “TTLABS Accredited” symbol or other reference to TTLABS accreditation.					
6.0 Calibration Labels					
6.1 Calibration labels containing the “TTLABS Accredited” symbol may be affixed only to equipment that has been calibrated by the accredited calibration laboratory.					
6.2 Calibration labels containing the “TTLABS Accredited” symbol shall include at least the following information:					
6.2.1 The name of the accredited calibration laboratory or its TTLABS Certificate number;					
6.2.2 The instrument identification;					
6.2.3 The date of the current calibration;					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
6.2.4 Cross reference to the calibration certificate issued with respect to this calibration.					
7.0 Advertising, Publicity, and Business Solicitation					
7.1 Accredited laboratories may incorporate statements concerning their accreditation in publicity and/or advertising materials, including brochures and organization publications, technical literature, business reports, web sites and quotations or proposals for work.					
7.2 The use of the “TTLABS Accredited” symbol or other reference to TTLABS used to promote accreditation enhances the reputation and value of accreditation for all stakeholders. It is the responsibility of the accredited laboratories to ensure that there is no misrepresentation of the accreditation status and that the accreditation process is not brought into disrepute.					
7.3 The accreditation claim shall be related only to the testing or calibration that is covered under the TTLABS Scope of Accreditation, and not with any other activities in which the laboratory or its parent organization are involved.					
7.4 TTLABS accreditation is site specific. The accreditation claim shall be related only to the specific laboratory location that is covered under the TTLABS Scope of Accreditation, and not with any other non-accredited locations.					
7.5 In proposals or quotations, the accredited laboratory shall distinguish tests or calibrations that are covered under the TTLABS Scope of Accreditation from those that are not covered.					
7.6 Where the “TTLABS Accredited” symbol is printed on letterhead or other corporate stationery, such stationery shall not be used for work proposals, quotes, reporting of test or calibration results exclusively outside the TTLABS Scope of Accreditation, or certifying a product or other item.					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
7.7 The “TTLABS Accredited” symbol or accreditation claim shall not be affixed to a material, item or product (or related part, including packaging), or used to imply that an item or product has been certified.					
7.8 If the “TTLABS Accredited” symbol is included in literature relating to a product, the symbol must appear directly adjacent to the reference to the accredited calibration or testing laboratory and it must be clearly stated that inclusion of the symbol does not imply certification/approval of the products calibrated or tested.					
7.9 The “TTLABS Accredited” symbol shall not be displayed on business cards in a manner that might imply personnel certification.					
8.0 Misuse of the “TTLABS Accredited” Symbol or Accreditation Status					
8.1 Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited and applicant laboratory representatives not to misrepresent their accredited status under any circumstances.					
8.2 If there are questions, the laboratory should submit intended uses of the symbol, draft advertisements, and/or any other accreditation claims to TTLABS Headquarters for advance review.					
8.3 Upon suspension or termination of accreditation, a laboratory must immediately cease to issue calibration certificates, test reports, and test certificates displaying the symbol and shall cease publishing documents containing the symbol.					

TO BE SIGNED BY THE AUTHORIZED REPRESENTATIVE OF THE LABORATORY:

We understand and agree to abide by the requirements contained in the “Reference to TTLABS Accredited Status – TTLABS Advertising Policy” once our laboratory becomes TTLABS accredited.

Print Name: _____ Signature: _____ Date: _____

TTLABS POLICY ON TRACEABILITY OF MEASUREMENT
(ADDENDUM TO THE ASSESSOR CHECKLIST: GENERAL CRITERIA)

(Effective April 2004)

Accredited laboratories are required to meet the following additional requirements contained in the TTLABS Policy on Measurement Traceability

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
TTLABS Policy on Traceability of Measurement					
T1. All calibrations and verifications of measuring and test equipment, reference standards, and reference materials shall be conducted by accredited calibration laboratories (in some instances an accredited testing laboratory may also be able to satisfy traceability requirements) or by a recognized national metrology institute.					
T2. Calibrations or verifications must be documented in a calibration certificate or report endorsed by a recognized accreditation body's symbol, or otherwise makes reference to accredited status.					
T3. Laboratories shall define their policy for achieving measurement traceability. This policy shall be in compliance with this policy document.					
T4. Where uncertainty calculations are applicable, testing and calibration laboratories shall calculate measurement uncertainty in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties shall be supported by uncertainty budgets, and they shall be represented as expanded uncertainties typically using a coverage factor of k=2 to approximate the 95% confidence level. (Refer to TTLABS's <i>Interim Policy on Measurement Uncertainty for Testing Laboratories</i> , April 2004)					
T5. If a calibration certificate or report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement shall be accompanied by an explanation of the meaning of the uncertainty statement. (For example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.)					

Requirement	Compliance			Reference	Comments [Reserved for TTLABS Assessor]
	Y	N	NA		
T6. TURs shall be calculated using the expanded uncertainty of the measurement, not the “collective uncertainty of the measurement standards”.					
T7. Implicit uncertainty statements (generally expressed in terms of a TUR) shall be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition the coverage factor and confidence level shall be stated.					
T8. Calibration reports and certificates issued by TTLABS-accredited calibration laboratories shall contain a traceability statement.					
T9. All in-house calibrations shall be supported by the following minimal set of elements:					
a) The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time;					
b) The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;					
c) The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute;					
d) The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;					
e) Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard.					