

**ICAVL STANDARDS
FOR ACCREDITATION IN
NONINVASIVE VASCULAR TESTING**

**PART II
VASCULAR LABORATORY OPERATIONS**

INTRACRANIAL CEREBROVASCULAR TESTING

Section 1 - Instrumentation

STANDARD - Instrumentation

1.1 Transcranial Doppler (TCD) or Transcranial Duplex must be provided as instrumentation.

Transcranial Doppler, through the use of imaging and/or non-imaging techniques, utilizes directional-pulsed wave spectral Doppler to estimate blood flow velocities in the intracranial arteries by insonation through acoustic windows. The necessary component, whether using imaging or non-imaging techniques, is the ability to assess intracranial vessel hemodynamics through blood flow velocity information so that the presence, location, and extent of disease can be evaluated.

Required Instrument Characteristics

- 1.1.1 Transducer frequencies appropriate for the vessels must be available for spectral Doppler.
- 1.1.2 Range-gated Doppler is provided with the ability to adjust the depth of the range gate within the area of interest.
- 1.1.3 The instrument must provide a visual display and an audible output as well as a permanent recording of the spectral Doppler waveform.

Section 2 - Indications

STANDARD - Indications

2.1 Transcranial cerebrovascular testing is performed for appropriate clinical indications.

Required Characteristics

2.1.1 The indication for testing must be documented.

Comment: Generally accepted indications will vary depending on clinical considerations that are provided by the referring health care provider and in some instances can only be assessed at the time of examination.

Appropriate indications for TCD examination includes, but are not limited to; arterial stenosis, **occlusion** or spasm detection, **vasomotor reactivity**, collateral blood flow patterns, cerebral embolization, **right-to-left shunt detection**, **peri-procedural or surgical monitoring**, **cerebral circulatory arrest**, or cerebrovascular **events** that result in abnormal cerebral hemodynamics.

Section 3 - Techniques and Documentation of Examination Performance

STANDARD - Techniques for Examination Performance

3.1 Appropriate techniques must be used for evaluation of the intracranial cerebrovascular circulation to assess the presence and severity of any abnormalities and to document their nature, location, extent and severity.

Required Characteristics

3.1.1 Transcranial Doppler is used to acquire relevant hemodynamic data from the major intracranial vasculature.

3.1.1.1 The laboratory must have a written protocol to determine the anatomic extent of the studies. A complete examination includes bilateral evaluation of anterior and posterior circulations including flow detection via temporal, orbital, foraminal, and (when appropriate) submandibular windows.

3.1.1.2 The laboratory protocol must define the extent of power reduction to be used for transorbital examinations. **For patient safety, the output power must not exceed 10% of maximum emitted power or 17 mW per cm² or equivalent measurements.**

3.1.1.3 Limited examinations may be performed for an appropriate or recurring indication. The reasons for a limited examination must be documented.

3.1.1.4 Transcranial Doppler is performed through the appropriate anatomical acoustic windows.

3.1.1.5 Spectral Doppler waveforms, transducer orientation and range gate depth are used to identify major vessels. With duplex examination, the color flow map may aid in vessel identification.

3.1.2 Elements of study performance must include, but are not limited to:

3.1.2.1 Performance of the examination according to the written and appropriate laboratory specific protocol

3.1.2.2 Proper patient positioning

3.1.2.3 Appropriate transducer selection and placement

3.1.2.4 Optimization of equipment gain and display settings

3.1.2.5 Proper sample volume size, depth and positioning

3.1.2.6 Proper measurement of spectral velocities

STANDARD – Required Documentation of Examination

3.2 Intracranial cerebrovascular examinations must be comprehensive and include standard components that provide sufficient documentation for interpretation.

Required Characteristics

3.2.1 A written protocol must be in place that defines the components and documentation of the intracranial cerebrovascular examination and the number of samples to be recorded. The protocol should also describe how the entire course of accessible portions of the anterior and posterior circulations is obtained.

3.2.1.1 As a minimum, the written protocol for complete examination requires the spectral Doppler sampling of the following segments:

- Intracranial internal carotid arteries
- A1 segment of the Anterior cerebral arteries
- M1-proximal M2 Middle cerebral arteries
- P1 or P2 Posterior cerebral arteries
- Ophthalmic artery
- Internal carotid artery siphon
- Distal internal carotid artery on the neck (when appropriate)
- Distal vertebral arteries
- Proximal and distal Basilar artery

3.2.1.2 For each sample site required in the protocol, a velocity spectrum representing the highest detected velocity is recorded.

3.2.1.2.1 Documentation of areas of abnormal vascular segments must include representative waveforms recorded proximal to, within and distal to any suspected abnormality.

3.2.1.3 Failure to obtain a velocity signal in a required artery is documented

Comment: When detected, velocity data from the anterior and/or posterior communicating arteries are documented.

3.2.2 Additional written protocols must be in place defining the specific requirements of any other types of TCD examinations performed in the laboratory (example: embolus detection, CO₂ reactivity and testing for shunts).

Section 4 - Diagnostic Criteria and Interpretation

STANDARD - Diagnostic Criteria

4.1 Interpretation of the Intracranial Cerebrovascular Doppler examination must use validated diagnostic criteria to assess the presence of disease, and to document its location, extent and severity.

Required Characteristics

4.1.1 Diagnostic criteria must be laboratory specific and documented. These criteria can be based on published reports or internally generated and internally validated as outlined in Section 6.

4.1.2 There must be criteria for interpretation of the depth of the sample volume, the presence and direction of blood flow, and the Doppler spectral characteristics.

STANDARD – Interpretation

4.2 The interpretation and report that is generated from the examination findings and diagnostic criteria must state the absence or presence of abnormalities in the vessels that were investigated. Disease, if present, must be characterized according to its location, extent and severity.

Comment: For the required characteristics of interpretation/final report, refer to Section 4 of the *ICAVL Standards, Part I: Vascular Operations – Organization*.

Section 5 - Procedure Volumes

STANDARD - Procedure Volumes

5.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually. In some settings, laboratories may perform quality examinations with lower volumes. These laboratories will be required to demonstrate competence through the submission of additional case studies as required by the ICAVL accreditation application.

Required Characteristics

5.1.1 Records must be maintained that permit evaluation of annual procedure volumes. These records must include information on the indication, test(s) performed and the findings.

Section 6 - Quality Assurance

STANDARD - Correlation and Confirmation of Results

6.1 Results of TCD examinations must be regularly correlated with an appropriate reference standard.

Required Characteristics

- 6.1.1 The laboratory must have a written procedure for regular correlation of transcranial Doppler examinations with angiographic findings produced by digital subtraction arteriography, contrast-enhanced computed tomography, or magnetic resonance angiography, or other appropriate correlative measure (i.e. echocardiography for shunts, clinical examination for brain death, etc). The correlation must be reported using the categories or abnormalities defined by the diagnostic criteria utilized by the laboratory.
- 6.1.2 A minimum of 30 separate examinations, including normal and abnormal intracranial studies, must be correlated every three years. A minimum of 10 of the correlating studies must include abnormal intracranial findings. These studies must have been done within the three years preceding the submission of the application.
- Comment:** TCD ordered for conditions other than stenotic disease may be correlated with appropriate alternative reference standards. (e.g. echocardiography for shunt testing).
- 6.1.3 The correlation between TCD and the appropriate reference standard studies should demonstrate greater than 70% agreement for each indication.
- 6.1.4 Documentation of correlation must be maintained.
- 6.1.5 Procedures must be in place for ongoing dissemination of information to both medical and technical personnel of the laboratory as required in Section 6 of the *ICAVL Standards, Part I: Vascular Operations – Organization*.