

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

**PART II
VASCULAR LABORATORY OPERATIONS**

EXTRACRANIAL CEREBROVASCULAR TESTING

Section 1 - Instrumentation

STANDARD – Instrumentation

1.1 Duplex ultrasonography with color flow Doppler must be provided as instrumentation.

Duplex ultrasonography combines real-time gray scale imaging with analysis of the angle corrected Doppler spectrum from a selected portion of the image. Gray scale imaging allows imaging of the vessel wall and detection of plaque or other diseases affecting vessels. Spectral Doppler is quantitative and is able to measure hemodynamic changes that vary according to the severity of disease. Color Doppler imaging provides a qualitative image of normal and abnormal vessel hemodynamics and is able to detect the course of blood vessels and narrowing within vessels.

Required Instrument Characteristics

- 1.1.1 A range of imaging frequencies appropriate for the vessels and structures evaluated must be available.
- 1.1.2 Doppler frequencies appropriate for the vessels evaluated must be available.
- 1.1.3 Range-gated Doppler must be provided with the ability to adjust the position of the range gate within the area of interest.
- 1.1.4 The Doppler angle must be measurable and adjustable.
- 1.1.5 The instrument must provide a visual display and an audible output, as well as a permanent recording of the Doppler waveform and image.

Section 2 - Indications

STANDARD - Indications

2.1 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 extracranial duplex testing include, but are not limited to: evaluation of patients with **stroke**, transient ischemic attack, amaurosis fugax, non-hemispheric neurologic symptoms, the presence of a carotid bruit, pulsatile neck mass, and known carotid artery stenosis based on prior testing.

Section 3 - Techniques and Documentation of Examination Performance

STANDARD – Techniques for Examination Performance

3.1 Appropriate techniques must be used for evaluation of the extracranial 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 A complete extracranial study is bilateral and evaluates the entire course of the accessible portions of the common carotid arteries (CCA) and internal carotid arteries (ICA). The external carotid arteries (ECA) and vertebral arteries are identified and Doppler spectral analysis is performed.

3.1.1.1 The laboratory must have a written protocol to determine the anatomic extent of the study.

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

3.1.1.3 Both imaging and Doppler information are used to identify vessels.

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

- 3.1.2.1 Performance of a duplex examination according to the written 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 and positioning
- 3.1.2.6 An angle of 60 degrees or less with respect to the vessel wall or direction of blood flow
- 3.1.2.7 Proper measurement of spectral velocities

Comment: Measurement of bilateral arm systolic blood pressures and/or recording of subclavian artery velocity waveforms are recommended as a part of the complete examination.

STANDARD – Required Documentation of Examination

3.2 Extracranial Cerebrovascular duplex ultrasound 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 extracranial cerebrovascular examination. **The entire course of the accessible portions of the CCA and ICA must be evaluated.** The protocol **must** also describe **how** color-coded Doppler is utilized to supplement gray scale imaging and spectral Doppler. If other flow imaging modes (e.g. power Doppler) are used, the protocol **must** describe how they are utilized.

- 3.2.1.1 Representative **long axis gray scale** images must be documented as required by the protocol and must include at a minimum images of the:
- CCA
 - ICA
 - carotid bifurcation
- 3.2.1.2 Representative spectral Doppler waveforms must be documented as required by the protocol and must include at a minimum waveforms taken from:
- **Proximal CCA**
 - **Mid/distal CCA**
 - **Proximal ICA**
 - **Distal ICA, sampling as distally as possible**
 - One site in the ECA
 - One site in the vertebral
- 3.2.1.3 Documentation of areas of suspected stenosis must include representative waveforms recorded at and distal to the stenosis.
- 3.2.1.4 Representative color coded Doppler images must be documented as required by the protocol.

Section 4 - Diagnostic Criteria and Interpretation

STANDARD - Diagnostic Criteria

4.1 Interpretation of the Extracranial Cerebrovascular duplex 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 gray scale images, spectral Doppler and when reported, plaque **description** and color-coded Doppler images.

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, etiology, 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 Extracranial Cerebrovascular duplex examinations must be regularly correlated with angiographic or surgical findings.

Required Characteristics

- 6.1.1 The laboratory must have a written procedure for regular correlation of carotid duplex examinations with angiographic findings produced by digital subtraction arteriography, contrast-enhanced computed tomography, or magnetic resonance angiography. The correlation must be reported using the categories of stenosis defined by the diagnostic criteria utilized by the laboratory. Surgical correlations may be used when angiographic correlation is not available.
 - 6.1.1.1 A minimum of 30 internal carotid arteries must be correlated every three years. These studies must have been done within the three years preceding the submission of the application.
 - 6.1.1.2 The correlation matrix should demonstrate greater than 70% agreement.
- 6.1.2 Documentation of correlation must be maintained.

Comment: If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered.
- 6.1.3 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*