

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

**PART VII  
VASCULAR LABORATORY OPERATIONS**

**SCREENING EXAMINATIONS**

**Section 1 - Instrumentation**

**STANDARD - Instrumentation**

**1.1 Duplex ultrasonography with color flow Doppler imaging must be provided as instrumentation for extracranial cerebrovascular screening examinations; color flow Doppler imaging is considered complementary for aortic aneurysm screening examinations.**

**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 of at least 3.0 MHz 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 spectral Doppler waveforms and images

**1.2 Single level limb pressures as screening for peripheral arterial disease must be performed with appropriate instrumentation.**

**Required Instrument Characteristics**

- 1.2.1 Cuffs of varying width appropriate to the limb segment to be evaluated must be used
- 1.2.2 A appropriate instrument for blood flow detection must be used

- 1.2.3 Pressure measurements must be recorded in mm Hg

## **Section 2 - Participant Selection**

### **STANDARD - Participant Selection**

#### **2.1 Risk factors for vascular disease must be assessed and documented prior to or at the time of testing.**

Screening examinations to determine the presence or absence of vascular disease are performed in participants without specific signs or symptoms. Screening guidelines for the appropriate selection of participants should be based upon contemporary scientific publications, and the use of screening examinations in low risk populations has not been shown to be scientifically valid. Screening cannot replace diagnostic examinations for symptomatic individuals.

## **Section 3 - Techniques and Components of Screening Examination Performance**

### **STANDARD - Techniques for Examination Performance**

#### **3.1 Appropriate techniques must be used for all screening examinations.**

##### **Required Characteristics**

- 3.1.1 Laboratories performing screening examinations must have a written protocol documenting the extent of the study
- 3.1.2 Elements of study performance must include, but are not limited to:
  - 3.1.2.1 Performance of screening examinations according to the written laboratory-specific protocol
  - 3.1.2.2 Proper patient positioning
  - 3.1.2.3 Appropriate transducer and/or blood pressure cuff selection and placement when applicable
  - 3.1.2.4 Optimization of equipment gain and display settings when applicable
  - 3.1.2.5 Proper sample volume size and positioning when applicable

3.1.2.6 A Doppler angle of 60 degrees or less when applicable

3.1.2.7 Proper measurement of spectral Doppler velocities when applicable

## **STANDARD - Components of Screening Examinations**

### **3.2 Screening examinations must include standard components.**

#### **Required Characteristics**

3.2.1 A written protocol must be in place that defines the components and documentation of the extracranial cerebrovascular screening examination

3.2.1.1 Representative spectral Doppler waveforms must be permanently recorded and must include at a minimum:

- **Normal examination:** One site in the proximal ICA with peak systolic and end diastolic velocity measurements
- **Abnormal examination:** Peak systolic and end diastolic velocity measurements documenting area(s) of significant findings in accordance with the laboratory diagnostic criteria

3.2.2 A written protocol must be in place that defines the components and documentation of the peripheral arterial screening examination

3.2.2.1 Measurement of lower extremity systolic blood pressure must be recorded from at least the ankle level

- Measurement of upper extremity (brachial artery) systolic pressures must be recorded for both arms and the higher of the two pressures used to calculate the Ankle Brachial Index (ABI)
- Measurement of ankle systolic pressures must be recorded bilaterally for the distal posterior tibial (PT) artery and distal anterior tibial / dorsalis pedis (DP) artery and the higher of the two pressures on each side used to calculate the ABI

Additional useful information regarding the presence of disease may be obtained by recording flow waveforms at the level of the ankles as well as by measuring great toe systolic pressures, particularly in cases when the ankle systolic pressures (ABIs) may be non-diagnostic.

- 3.2.3 A written protocol must be in place that defines the components and documentation of the abdominal aortic screening examination
- 3.2.3.1 Gray scale - Representative gray scale images of the aorta must be permanently recorded and must include at a minimum:
- **Normal examination:** One transverse view with diameter measurements of the aortic segment of maximum diameter
  - **Abnormal examination:** Transverse view(s) with diameter measurements of the aortic segment(s) of maximum diameter and one transverse view with diameter measurements of the non-dilated aorta for comparison

## **Section 4 - Diagnostic Criteria and Interpretation**

### **STANDARD - Diagnostic Criteria**

#### **4.1 Interpretation of the screening examinations must use standardized criteria to assess the presence of disease.**

##### **Required Characteristics**

- 4.1.1 There must be written objective criteria for extracranial cerebrovascular screening examinations
- 4.1.1.1 At a minimum these criteria must include these four categories:
- Absence of disease (Normal)
  - Presence of disease of no overall significance (according to the laboratory-specific diagnostic criteria)
  - Presence of disease of overall significance (according to the laboratory-specific diagnostic criteria)
  - Occlusion
- 4.1.2 There must be written objective criteria for peripheral arterial screening examinations
- 4.1.2.1 At a minimum these criteria must include these three categories:
- Absence of disease (according to the laboratory-specific diagnostic criteria)
  - Presence of disease (according to the laboratory-specific diagnostic criteria)
  - Non-diagnostic ABIs

4.1.3 There must be written objective criteria for abdominal aortic aneurysm screening examinations

4.1.3.1 At a minimum these criteria must include these two categories:

- Absence of aneurysmal disease
- Presence of aneurysmal disease (according to the laboratory-specific diagnostic criteria)

## **STANDARD - Interpretation**

**4.2 The interpretation and report that is generated from the screening examination must state the absence or presence of disease in the vessels that were investigated.**

4.2.1 Documentation of all screening results, both negative and positive, must be maintained in the laboratory

4.2.2 A report or document that describes the results of the examination findings and recommended follow-up must be provided to the participant and/or participant's physician

4.2.3 Educational materials describing the nature of vascular screening and the significance of normal and abnormal results must be provided to the participant

## **Section 5 - Procedure Volumes**

### **STANDARD - Procedure Volumes**

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

#### **Required Characteristics**

5.1.1 Records must be maintained that permit evaluation of annual screening examination volumes

In general, a laboratory should perform a minimum of 50 screening examinations annually for each area of screening performed. In some settings, laboratories may perform quality screening with lower volumes. These laboratories will be required to demonstrate competence through the submission of additional case studies.

## Section 6 - Quality Assurance

### STANDARD - Correlation and Confirmation of Results

#### 6.1 Results of screening examinations must be regularly correlated.

##### Required Characteristics

- 6.1.1 The laboratory must have a written protocol for regular correlation of each type of screening examination performed to an appropriate diagnostic standard; whenever possible, correlation to radiographic, surgical pathology and patient outcome must be documented
- 6.1.2 The correlation must be reported using the categories defined in the laboratory-specific diagnostic criteria
  - 6.1.2.1 A minimum of 15 correlations for each type of screening examination performed is required in a three-year period. These screening examinations must have been done within the three years preceding the submission of the application
  - 6.1.2.2 Correlation data for each type of screening examination must include participants with normal and abnormal findings
  - 6.1.2.3 An accuracy greater than 70% is required for each type of screening examination performed
- 6.1.3 Documentation of correlation must be maintained
- 6.1.4 Procedures must be in place for ongoing dissemination of correlation findings and other relevant information to both medical and technical personnel of the laboratory as required in Section 6 of the *ICAVL Standards, Part I: Vascular Operations – Organization*.