

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

**PART II  
VASCULAR LABORATORY OPERATIONS**

**VISCERAL VASCULAR 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 Visceral vascular 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 visceral vascular testing include, but are not limited to; arterial insufficiency, aneurysms/pseudoaneurysms, follow-up of arterial reconstruction, endovascular procedures or surgical intervention, evaluation of transplants, shunts, suspected fistulae, venous obstruction or occlusion, suspected portal hypertension or renal hypertension, or renal insufficiency

## Section 3 - Techniques and Documentation of Examination Performance

### STANDARD - Techniques for Examination Performance

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

##### Required Characteristics

3.1.1 Visceral vascular testing comprises several distinct tests because different indications require different vascular beds to be evaluated.

3.1.1.1 Each visceral vascular system requires several vessels to be examined. Some tests also require gray scale imaging of the appropriate organ.

3.1.1.1.1 Visceral vascular tests comprise the following vessel groups:

- A.) Mesenteric arterial system
- B.) Hepatoportal system
- C.) Renal vasculature
- D.) Renal transplants
- E.) Liver transplant

- 3.1.1.2 Both imaging and Doppler information are used to identify vessels.
- 3.1.1.3 The entire course of the accessible portions of each visceral vessel should be examined.
- 3.1.1.4 The laboratory must have a written protocol to determine the extent of the study and the appropriate documentation of normal and abnormal studies.
  - 3.1.1.4.1 Limited examinations may occur for an appropriate or recurring indication. The reason for a limited examination must be documented.

3.1.1.5 Laboratories can seek accreditation in one or more visceral vascular testing areas.

3.1.1.6 Laboratories must seek accreditation in all of the visceral vascular tests they perform.

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

- 3.1.2.1 Performance of examination according to the written, laboratory specific protocol
- 3.1.2.2 Proper patient positioning
- 3.1.2.3 Patient preparation if appropriate
  - 3.1.2.3.1 Patient preparation may be necessary in order to minimize abdominal gas. This may include fasting and/or gas reducing medication.
- 3.1.2.4 Appropriate transducer selection and placement
- 3.1.2.5 Optimization of equipment gain and display settings
- 3.1.2.6 Proper sample volume size and positioning
- 3.1.2.7 An angle of 60 degrees or less with respect to the vessel wall and/or, direction of blood flow
- 3.1.2.8 Proper measurement of spectral velocities

## STANDARD – Required Documentation of Examination

### 3.2 Visceral Vascular examinations must 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 complete examination. The protocol should 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 should describe how they are utilized.
- 3.2.1.1 The entire course of the accessible portions of each visceral vessel should be examined. Representative gray scale and/or color Doppler images from the following vessel groups must be documented as required by the protocol. Abnormalities require additional images that demonstrate the type and severity of the abnormality present.
- A.) Mesenteric arterial system
    - Adjacent aorta
    - Celiac artery
    - Superior mesenteric artery
    - Inferior mesenteric artery
  - B.) Hepatoportal system
    - Intrahepatic portal vein
    - Extrahepatic portal vein
    - Hepatic veins
    - Inferior vena cava
    - Adjacent liver parenchyma
    - Portosystemic shunts or collateral pathways (when present)
  - C.) Renal system
    - Adjacent aorta
    - Renal arteries
    - Renal veins
    - Gray scale pole to pole renal length measurement

**Comment:** A complete renal vasculature examination includes bilateral evaluation.

#### D.) Renal transplants

- Donor artery
- Transplant renal artery
- Transplant renal vein
- Gray scale images of transplant kidney and peri-transplant region

#### E.) Liver transplants

- Intrahepatic portal vein
- Extrahepatic portal vein
- Hepatic veins
- Hepatic artery
- Inferior vena cava
- Gray scale images of transplant liver and peri-transplant region

3.2.1.2 The entire course of the accessible portions of each visceral vessel should be examined. Representative spectral Doppler waveforms must be documented as required by the protocol and must include at a minimum waveforms taken from:

#### A.) Mesenteric arterial system

- Adjacent aorta
- Celiac artery origin
- Splenic and hepatic arteries when appropriate
- Superior mesenteric artery origin
- Proximal superior mesenteric artery
- Inferior mesenteric artery

#### B.) Hepatoportal system

- Main portal vein
- Right portal vein
- Left portal vein
- Superior mesenteric vein
- Splenic vein
- Right, left and middle hepatic veins
- Inferior vena cava
- Portosystemic shunts (when present)
- TIPS requires angle corrected waveforms with velocities from:
  - Portal vein inflow
  - Portal end of stent
  - Mid stent
  - Hepatic end of stent
  - Hepatic vein outflow

### C.) Renal system

- Adjacent aorta
- Proximal main renal artery
- Mid main renal artery
- Distal main renal artery
- Parenchymal/hilar arteries (when appropriate)
- Accessory renal artery when present
- Renal veins (when appropriate)

**Comment:** A complete renal vasculature examination includes bilateral evaluation.

### D.) Renal transplants

- Donor artery
- Arterial anastomosis
- Proximal transplant renal artery
- Distal transplant renal artery
- Parenchymal vessels
- Transplant renal vein
- Renal vein anastomosis

### E.) Liver Transplants

- Donor artery
- Main hepatic artery
- Hepatic veins
- Portal vein anastomosis
- Portal vein
- Inferior vena cava

3.2.1.3 Abnormalities require additional images that demonstrate the type and severity of the abnormality present. Documentation of areas of suspected stenosis must include representative waveforms recorded at and distal to the stenosis.

## Supplemental Testing

### 3.2.2 Abdominal Aorta Duplex

**Comments:** Because abdominal aortic duplex is not a true visceral vascular examination, laboratories performing aorta duplex as the primary abdominal examination in their laboratory cannot achieve visceral vascular accreditation. Aorta duplex is considered a supplemental examination and if performed in the laboratory should be submitted as a supplemental examination as directed by the *ICAVL* accreditation application.

3.2.2.1 A written protocol must be in place that defines the components and documentation of the complete examination.

3.2.2.1.1 Representative gray scale and/or color Doppler images from the following vessel groups must be documented as required by the protocol and must include the following with additional documentation of any abnormalities:

- Aorta – Proximal, mid and distal transverse views with diameter measurements
- Aorta – Proximal, mid and distal longitudinal views
- Transverse view of the common iliac arteries at the aortic bifurcation
- Documentation of aneurysms, if present, must include representative gray scale images at, proximal to and distal to the aneurysm.

3.2.2.2 Representative spectral Doppler waveforms must be documented as Required by the protocol and must include at a minimum waveforms taken from:

- One site in the aorta as described in the laboratory protocol
- Other aorto-iliac sites as appropriate

3.2.2.3 Representative color coded Doppler images must be documented as required by the laboratory protocol.

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

### **STANDARD - Diagnostic Criteria**

**4.1 Interpretation of the Visceral Vascular duplex examination must use validated diagnostic criteria to assess the presence of disease, and to document its location, etiology, 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 utilized, plaque morphology, and color coded Doppler images specific for each examination performed.

## **STANDARD - Interpretation**

**4.2 The findings generate an interpretation and report that indicates 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 Visceral Vascular 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 visceral vascular 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 and/or disease defined by the diagnostic criteria utilized by the laboratory. Surgical correlations may be used when angiographic correlation is not available.
- 6.1.2 A minimum of 15 patient examinations are to be correlated. These correlations must reflect a mix of all vessel groups performed by the laboratory and have been completed within the three years preceding submission of the application.
  - 6.1.1.2 The correlation matrix should demonstrate greater than 70% agreement.
- 6.1.3 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.
- 6.1.4 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*.