Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

ST - P0000 - INITIAL COMMENTS

Title  INITIAL COMMENTS
Statute or Rule  
Type  Memo Tag

Regulation Definition

These guidelines are meant solely to provide guidance to surveyors in the survey process.

ST - P0002 - NOTICE OF FEES CHARGED

Title  NOTICE OF FEES CHARGED
Statute or Rule  483.312, FS
Type  Rule

Regulation Definition

Each center licensed under this part shall employ a medical director who is either a physician licensed under chapter 458 or an osteopathic physician licensed under chapter 459 and who, as part of her or his usual medical practice, interprets electrocardiograms. A consumer multiphasic health testing center must display at all times in a prominent place at the center a list of all tests and the specific fees charged for those tests. The center must provide to each patient before the collection of a specimen or the administration of a test the specific fees charged for the test.
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ST - P0003 - MEDICAL DIRECTOR OF CENTER

Title MEDICAL DIRECTOR OF CENTER
Statute or Rule 483.312(1) FS
Type Rule

**Regulation Definition**

In a contract multiphasic health testing center, electrocardiograms and X rays must be read and interpreted by the medical director of the contract center or respectively by a board-certified cardiologist or radiologist authorized by the medical director to read and interpret the electrocardiograms and X rays and report results to the medical director.

**Interpretive Guideline**

ST - P0004 - COLLECTION AND TRANSMITTAL OF SPECIMENS

Title COLLECTION AND TRANSMITTAL OF SPECIMENS
Statute or Rule 483.308(2) FS
Type Rule

**Regulation Definition**

Consumer multiphasic health testing centers shall report the results of an analysis directly to the medical director of the center that requested it and shall forward the results to the person from whom the specimen was collected within 5 days after the date the specimen was collected. When test results deviate significantly from established ranges, indicating the presence of a potential pathological condition, the contract multiphasic health testing center must forward the results to the person from whom the specimen was collected and the person’s designated physician within 5 days after the date the specimen was collected. Complete results of contract multiphasic health testing must be forwarded to the medical
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

director of the contracting employer within 30 days after the date the specimen was collected.

<table>
<thead>
<tr>
<th>ST - P0100 - LICENSURE PROCEDURE</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong> LICENSURE PROCEDURE</td>
</tr>
<tr>
<td><strong>Statute or Rule</strong> 59A-6.020(1) FAC</td>
</tr>
<tr>
<td><strong>Type</strong> Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

A license from the agency is required to conduct, maintain or operate a multiphasic health testing center in this state, unless such center is exempt from licensure as specified in Section 483.285, F.S.

**Interpretive Guideline**

<table>
<thead>
<tr>
<th>ST - P0102 - LICENSURE PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong> LICENSURE PROCEDURE</td>
</tr>
<tr>
<td><strong>Statute or Rule</strong> 59A-6.020 FAC</td>
</tr>
<tr>
<td><strong>Type</strong> Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

An applicant for licensure shall be designated by a distinctive name, and the name shall not be changed without first notifying the agency and receiving approval in writing for such change.

**Interpretive Guideline**

<table>
<thead>
<tr>
<th>ST - P0117 - LICENSURE PROCEDURE</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong> LICENSURE PROCEDURE</td>
</tr>
<tr>
<td><strong>Statute or Rule</strong> 59A-6.020(3) FAC</td>
</tr>
<tr>
<td><strong>Type</strong> Rule</td>
</tr>
</tbody>
</table>
Each license is valid only for the person or entity to whom it is issued and may not be sold, assigned, or transferred voluntarily or involuntarily. A license is not valid for any premises or mobile facility other than that for which originally issued. A center must be relicensed if a change of ownership occurs. Application for relicensure must be made to the agency 60 days prior to the change of ownership. When a multiphasic health testing center is leased by the owner to a second party for operation, said second party must apply for a new license. A copy of the lease agreement or signed statement showing which party is to be held responsible for the organization, operation and maintenance of the multiphasic health testing center shall be filed with the application. A license shall be returned to the agency immediately upon change of ownership or classification, suspension, revocation, or voluntary cessation of operations.

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>When a multiphasic health testing center is in compliance with rules, regulations and standards, a license which identifies the name and location of the multiphasic health testing center, will be issued. This license must be displayed in a conspicuous place on the center premises.</td>
<td></td>
</tr>
</tbody>
</table>

ST - P0119 - LICENSURE PROCEDURE

Title LICENSURE PROCEDURE
Statute or Rule 59A-6.020(7) FAC
Type Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>When a multiphasic health testing center is in compliance with rules, regulations and standards, a license which identifies the name and location of the multiphasic health testing center, will be issued. This license must be displayed in a conspicuous place on the center premises.</td>
<td></td>
</tr>
</tbody>
</table>
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

### ST - P0120 - LICENSURE PROCEDURE

<table>
<thead>
<tr>
<th>Title</th>
<th>LICENSURE PROCEDURE</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.020 FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

59A-6.020

(5) A separate license shall be required for each multiphasic health testing center when more than one (1) multiphasic health testing center, whether it be a fixed or mobile facility, is operated under the same ownership or management.

### ST - P0122 - LICENSURE PROCEDURE

<table>
<thead>
<tr>
<th>Title</th>
<th>LICENSURE PROCEDURE</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.020(6) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

A licensee shall notify the agency by certified mail of impending closure of a licensed center, thirty (30) days prior to such closure. The license shall be surrendered to the agency immediately following cessation of operations.

### ST - P0301 - STANDARDS OF PERFORMANCE

<table>
<thead>
<tr>
<th>Title</th>
<th>STANDARDS OF PERFORMANCE</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(1)(b) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>
The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

Employees are qualified by education, training and experience, certification, licensure or registration in their specialty to perform the testing procedures for which they are employed. Personnel must be licensed as required under Florida Statutes including Chapter 464, 483, Part IV, 468, Part IV, or 468, Part V, F.S., for their respective disciplines. Such training, licensure and experience shall be documented and maintained on the center premises during the tenure of such personnel and for two years thereafter.

The center must maintain current certification documenting that it is operated in compliance with local, state and federal law.

Title  STANDARDS OF PERFORMANCE
Statute or Rule  59A-6.022(2)(a) FAC
Type  Rule

Regulation Definition
The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

The center must maintain current certification documenting that it is operated in compliance with local, state and federal law.
ST - P0303 - STANDARDS OF PERFORMANCE

Title STANDARDS OF PERFORMANCE
Statute or Rule 59A-6.022(2)(b) FAC
Type Rule

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

Consumers are not denied multiphasic health testing by reason of race, creed, age, or national origin.

ST - P0304 - STANDARDS OF PERFORMANCE

Title STANDARDS OF PERFORMANCE
Statute or Rule 59A-6.022(2)(c) FAC
Type Rule

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

A system of accounting and record keeping is maintained that is consistent with Generally Accepted Accounting Principles as defined in Rule 21A61H1-20.007, Florida Administrative Code, F.A.C., April 21, 1991.
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

<table>
<thead>
<tr>
<th>Title</th>
<th>STANDARDS OF PERFORMANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(2)(d) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

**Interpretive Guideline**

Liability insurance is in force as referenced in paragraph 59A-6.020(2)(k), F.A.C.

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<table>
<thead>
<tr>
<th>Title</th>
<th>STANDARDS OF PERFORMANCE</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(4) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

**Interpretive Guideline**

The center is operated and maintained in a facility where the safety and health of consumers and employees are not endangered in accordance with this rule chapter.
<table>
<thead>
<tr>
<th>Title</th>
<th>STANDARDS OF PERFORMANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(8) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

The center uses equipment and procedures that meet the objective of the test to which the consumer is subjected and equipment is maintained in a satisfactory operating condition required by this rule chapter.

**ST - P0309 - STANDARDS OF PERFORMANCE**

<table>
<thead>
<tr>
<th>Title</th>
<th>STANDARDS OF PERFORMANCE</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(8) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

Clinical operation of the center shall be the responsibility of a physician licensed under Ch. 458 or 459, F.S. This physician shall serve as the medical director of the center.
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ST - P0310 - STANDARDS OF PERFORMANCE

Title STANDARDS OF PERFORMANCE
Statute or Rule 59A-6.022(9) FAC
Type Rule

Regulation Definition

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to subsection 59A-6.022(1), F.A.C., as are necessary to assure the safety and accuracy of tests given to consumers.

Requests for clinical laboratory analysis of specimens collected at the center shall bear the name of the medical director.

ST - P0402 - POLICIES AND PROCEDURES

Title POLICIES AND PROCEDURES
Statute or Rule 59A-6.022(3)(a) 1 FAC
Type Rule

Regulation Definition

A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

Requirements for specimen collection and processing.
ST - P0403 - POLICIES AND PROCEDURES

Title  POLICIES AND PROCEDURES
Statute or Rule  59A-6.021(3)(a)1 FAC
Type  Rule

**Regulation Definition**
A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

- Step by step performance of the procedure.

ST - P0404 - POLICIES AND PROCEDURES

Title  POLICIES AND PROCEDURES
Statute or Rule  59A-6.021(3)(a)2 FAC
Type  Rule

**Regulation Definition**
A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

- Remedial actions to be taken when instrument operation fails to meet the center's requirement for acceptability.
## ST - P0405 - POLICIES AND PROCEDURES

### Title
POLICIES AND PROCEDURES

### Statute or Rule
59A-6.022(3)(a) 4 FAC

### Type
Rule

#### Regulation Definition
A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

- Criteria for specimen storage and preservation to ensure specimen integrity until testing is completed or such specimen is forwarded to the laboratory that will perform the analysis.

#### Interpretive Guideline

## ST - P0406 - POLICIES AND PROCEDURES

### Title
POLICIES AND PROCEDURES

### Statute or Rule
59A-6.022(3)(a) 5 FAC

### Type
Rule

#### Regulation Definition
A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

- Pertinent literature references.
<table>
<thead>
<tr>
<th>ST - P0407 - POLICIES AND PROCEDURES</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
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<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

**Regulation Definition**

A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

Description of the course of action to be taken in the event a test system becomes inoperable.

**Interpretive Guideline**

Review manufacturer’s requirements to determine compliance regarding use and maintenance of equipment. Maintenance documentation is not required if no requirements are specified by the manufacturer.

<table>
<thead>
<tr>
<th>ST - P0408 - POLICIES AND PROCEDURES</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
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<tr>
<td><strong>Statute or Rule</strong></td>
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<tr>
<td><strong>Type</strong></td>
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</tbody>
</table>

**Regulation Definition**

A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:

Maintenance, calibration, quality control procedures and procedures for performing routine checks, daily function checks or other checks that assure proper operation of equipment and test methodologies.
### ST - P0409 - POLICIES AND PROCEDURES

**Title** POLICIES AND PROCEDURES  
**Statute or Rule** 59A-6.022(3)(a) 8 FAC  
**Type** Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including: Quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process.</td>
<td></td>
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</table>

### ST - P0410 - POLICIES AND PROCEDURES

**Title** POLICIES AND PROCEDURES  
**Statute or Rule** 59A-6.022(3)(a) 8(b) FAC  
**Type** Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. Written policies and procedures shall cover the following: Identification of persons responsible for the operation of the center.</td>
<td></td>
</tr>
</tbody>
</table>
Title  POLICIES AND PROCEDURES
Statute or Rule  59A-6.022(3)(a) 8(c) FAC
Type  Rule

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. Written policies and procedures shall cover the following:

Responsibilities of the medical director.

Title  POLICIES AND PROCEDURES
Statute or Rule  59A-6.022(3)(a) 8(d) 1 FAC
Type  Condition

A center shall have a current polices and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

Requests for clinical laboratory tests from persons authorized by Florida law to order tests may be accepted without adding the medical director's name to the test request.
ST - P0414 - POLICIES AND PROCEDURES

Title POLICIES AND PROCEDURES
Statute or Rule 59A-6.022(8)(d) 2 FAC
Type Rule

**Regulation Definition**

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

- Outside resources used by the center shall be pursuant to written agreement which must specify that the center assumes full responsibility for the services provided.

**Interpretive Guideline**

ST - P0415 - POLICIES AND PROCEDURES

Title POLICIES AND PROCEDURES
Statute or Rule 59A-6.022(3)(d) 2 FAC
Type Rule

**Regulation Definition**

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

- Neither the medical director nor any other employee of the center shall provide any diagnosis, consultation or treatment.
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**ST - P0416 - POLICIES AND PROCEDURES**

**Title** POLICIES AND PROCEDURES  
**Statute or Rule** 59A-6.022(3)(d) 4 FAC  
**Type** Rule

**Regulation Definition**  
A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

Consumers seeking clarification of their test results must be referred to their personal physician if they do not have a personal physician, the consumer shall be given the name, address and telephone number of the local county medical or osteopathic association or society.

**ST - P0417 - POLICIES AND PROCEDURES**

**Title** POLICIES AND PROCEDURES  
**Statute or Rule** 59A-6.022(3)(d) 5 FAC  
**Type** Rule

**Regulation Definition**  
A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

Written emergency procedures shall be established and every
Employee shall be familiar with these procedures.

### ST - P0418 - POLICIES AND PROCEDURES

<table>
<thead>
<tr>
<th>Title</th>
<th>POLICIES AND PROCEDURES</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(3)(d) 6 FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

- Reports which provide the results of tests shall not be revealed to individuals unauthorized by law to review them.

**Interpretive Guideline**

Examples of procedures that may be included in the emergency procedures include fire and disaster preparedness protocols and a procedure to call 911 in case of a medical emergency.

### ST - P0419 - POLICIES AND PROCEDURES

<table>
<thead>
<tr>
<th>Title</th>
<th>POLICIES AND PROCEDURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(3)(d) 7 FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover a protocol for center operation which shall include:

- Reports which provide the results of tests shall not be revealed to individuals unauthorized by law to review them.
<table>
<thead>
<tr>
<th>Title</th>
<th>POLICIES AND PROCEDURES</th>
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</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(3)(d) 7(e) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
<tr>
<td><strong>Regulation Definition</strong></td>
<td><strong>Interpretive Guideline</strong></td>
</tr>
<tr>
<td>A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test.</td>
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<tr>
<td>The procedures manual must be approved, signed and dated by the medical director annually.</td>
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<table>
<thead>
<tr>
<th>Title</th>
<th>POLICIES AND PROCEDURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(3)(a), 59A-6.002 7(f) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
<tr>
<td><strong>Regulation Definition</strong></td>
<td><strong>Interpretive Guideline</strong></td>
</tr>
<tr>
<td>A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test.</td>
<td></td>
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<tr>
<td>Each change in procedures must be approved, signed and dated by the current medical director.</td>
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</tbody>
</table>
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ST - P0422 - POLICIES AND PROCEDURES

Title POLICIES AND PROCEDURES
Statute or Rule 59A-6.022(3)(a) 7(g) FAC
Type Rule

**Regulation Definition**
A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test.

The center must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be maintained for two years after a procedure has been discontinued.

ST - P0423 - POLICIES AND PROCEDURES

Title POLICIES AND PROCEDURES
Statute or Rule 59A-6.022(3)(a) 7(h) FAC
Type Rule

**Regulation Definition**
A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers.

Written procedures shall be in effect to assure the prevention of infection.

Interpretive Guideline
### ST - P0424 - POLICIES AND PROCEDURES

**Title**: POLICIES AND PROCEDURES  
**Statute or Rule**: 59A-6.022(3)(a) FAC  
**Type**: Rule

**Regulation Definition**

A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers.

Written procedures shall be in effect to assure the prevention of infection. These procedures shall address and implement disposable syringes, needles and lancets must be used.

### ST - P0425 - POLICIES AND PROCEDURES

**Title**: POLICIES AND PROCEDURES  
**Statute or Rule**: 59A-6.022(3)(a) 2 FAC  
**Type**: Rule

**Regulation Definition**

Policies and Procedures. A center shall have a current policies and procedures manual for its operation that will assure the integrity of specimens taken, the accuracy of all tests given and the safety of consumers. As a minimum, written policies and procedures shall cover the following:

A written procedure shall be prepared for each test, outlining the objective of the test, the correct use of equipment, and the methodology for taking the test. The procedure manual must include the applicable test procedure including:
Procedures shall be established for the sterilizing of equipment that may transmit disease. Such equipment shall be sterilized after each test.

### ST - P0500 - PERSONNEL STANDARDS

**Title**  PERSONNEL STANDARDS  
**Statute or Rule**  59A-6.022(1)(a) FAC  
**Type**  Rule

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to Rule 59A-6.022(1), as are necessary to assure the safety and accuracy of tests given to consumers.

### ST - P0501 - PERSONNEL STANDARDS

**Title**  PERSONNEL STANDARDS  
**Statute or Rule**  59A-6.022(1)(c) FAC  
**Type**  Rule

**Regulation Definition**

The owner, administrator, or manager of the center shall retain such personnel qualified pursuant to Rule 59A-6.022(1), as are necessary to assure the safety and accuracy of tests given to consumers.
### Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

#### ST - P0600 - CLINICAL LABORATORIES

<table>
<thead>
<tr>
<th>Title</th>
<th>CLINICAL LABORATORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.021(10) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

Medical services provided outside the center, including clinical laboratory, pulmonary function, electrocardiograph and radiology, services shall be pursuant to written agreement between the center and the service provider which must specify that the center assumes full responsibility for the services provided.

**Interpretive Guideline**


#### ST - P0700 - RECORDS AND REPORTS

<table>
<thead>
<tr>
<th>Title</th>
<th>RECORDS AND REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.026 FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual's record.

**Interpretive Guideline**

Review a minimum sample of five test results.

#### ST - P0702 - RECORDS AND REPORTS

<table>
<thead>
<tr>
<th>Title</th>
<th>RECORDS AND REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.026(1)(a) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

**Regulation Definition**

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- A sequence number.

**ST - P0703 - RECORDS AND REPORTS**

**Title** RECORDS AND REPORTS

**Statute or Rule** 59A-6.026(1)(b) FAC

**Type** Rule

**Regulation Definition**

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- Name.

**ST - P0704 - RECORDS AND REPORTS**

**Title** RECORDS AND REPORTS

**Statute or Rule** 59A-6.026(1)(c) FAC

**Type** Rule
The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- Address
- Date of Birth
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record. As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:</td>
<td></td>
</tr>
<tr>
<td>Sex.</td>
<td></td>
</tr>
</tbody>
</table>

ST - P0707 - RECORDS AND REPORTS

**Title** RECORDS AND REPORTS

**Statute or Rule** 59A-6.026(1)(f) FAC

**Type** Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record. As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:</td>
<td></td>
</tr>
<tr>
<td>Laboratory test taken, including the date and time the specimen was collected and the date the test was returned, completed.</td>
<td></td>
</tr>
</tbody>
</table>
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

ST - P0708 - RECORDS AND REPORTS

Title  RECORDS AND REPORTS
Statute or Rule  59A-6.026(1)(g) FAC
Type  Rule

Regulation Definition

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- Laboratory used.

ST - P0709 - RECORDS AND REPORTS

Title  RECORDS AND REPORTS
Statute or Rule  59A-6.026(1)(h) FAC
Type  Rule

Regulation Definition

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- Tests performed and the identity of the individual performing
The test for all tests performed in the center.

ST - P0710 - RECORDS AND REPORTS

Title RECORDS AND REPORTS
Statute or Rule 59A-6.026(1)(i) FAC
Type Rule

Regulation Definition

The center shall maintain records on all consumers who have been tested. A system shall be established to insure the prompt location of each tested individual’s record.

As a minimum, the center shall maintain a record for a minimum of two years from the date of testing which shall contain the following items of information:

- Date test results were provided to the consumer.

ST - P0711 - RECORDS AND REPORTS

Title RECORDS AND REPORTS
Statute or Rule 59A-6.026(2) FAC
Type Rule

Regulation Definition

A copy of all test results and reports shall be maintained for a period of no less than two years.
### ST - P0801 - COLLECTION AND TRANSMITTAL OF SPECIMENS

**Title**  
COLLECTION AND TRANSMITTAL OF SPECIMENS

**Statute or Rule**  
59A-6.027(1)(a) FAC

**Type**  
Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
</table>
| No center shall collect specimens from the human body where prudent medical practice requires that such specimens only be collected during the course of a physical examination by a physician. The following procedures are prohibited:  

Papanicolaou Tests (PAP Smears) unless such test is collected by a physician licensed under Chapter 458 or 459, F.S.; |

### ST - P0802 - COLLECTION AND TRANSMITTAL OF SPECIMENS

**Title**  
COLLECTION AND TRANSMITTAL OF SPECIMENS

**Statute or Rule**  
59A-6.027(1)(b) FAC

**Type**  
Rule

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
</table>
| No center shall collect specimens from the human body where prudent medical practice requires that such specimens only be collected during the course of a physical examination by a physician. The following procedures are prohibited:  

Prothrombin Time. |
## ST - P0804 - COLLECTION AND TRANSMITTAL OF SPECIMENS

**Title**  
COLLECTION AND TRANSMITTAL OF SPECIMENS

**Statute or Rule**  
59A-6.027(3) FAC

**Type**  
Rule

### Regulation Definition

If clinical specimens are collected, each licensed center shall have an operating refrigerator, or other means of refrigeration, each capable of maintaining a temperature of 2-8 degrees centigrade for the proper storage of specimens. Refrigerator temperature readings shall be recorded each day of use and maintained for a minimum of two years.

### Interpretive Guideline


## ST - P0805 - COLLECTION AND TRANSMITTAL OF SPECIMENS

**Title**  
COLLECTION AND TRANSMITTAL OF SPECIMENS

**Statute or Rule**  
59A-6.027(4) FAC

**Type**  
Rule

### Regulation Definition

Each specimen must be sent to the testing laboratory for analysis as rapidly as possible, but no later than 12 hours after collection unless appropriate measures are taken to preserve the specimen.

### Interpretive Guideline


## ST - P0806 - COLLECTION AND TRANSMITTAL OF SPECIMENS

**Title**  
COLLECTION AND TRANSMITTAL OF SPECIMENS

**Statute or Rule**  
59A-6.027(1)(a) FAC

**Type**  
Rule
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

Regulation Definition
No specimen shall be collected and delivered at any time beyond which the integrity of such specimens is valid and will provide reliable results.

Interpretive Guideline

ST - P0807 - COLLECTION AND TRANSMITTAL OF SPECIMENS

Title COLLECTION AND TRANSMITTAL OF SPECIMENS
Statute or Rule 59A-6.027(4)(b) FAC
Type Rule

Regulation Definition
Appropriate measures shall be taken to assure specimen preservation where applicable and such measures shall be noted in the patient record specified under subsection 59A-6.026(1), F.A.C.

Interpretive Guideline

ST - P0808 - COLLECTION AND TRANSMITTAL OF SPECIMENS

Title COLLECTION AND TRANSMITTAL OF SPECIMENS
Statute or Rule 59A-6.027(5) FAC
Type Rule

Regulation Definition
Mobile centers must provide for proper transfer of laboratory specimens which shall include, but not be limited to, appropriate refrigeration.
### ST - P0809 - COLLECTION AND TRANSMITTAL OF SPECIMENS

<table>
<thead>
<tr>
<th>Title</th>
<th>COLLECTION AND TRANSMITTAL OF SPECIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.027(6) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**
Serum or plasma shall be removed from red blood cells in instances where results may be adversely affected by the presence of red blood cells.

### ST - P0900 - EQUIPMENT

<table>
<thead>
<tr>
<th>Title</th>
<th>EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(5) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**
All equipment used for testing purposes shall be in good working order. Documentation shall be provided that such equipment has been checked and calibrated for accuracy. The equipment shall be appropriate for the tests administered.
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

**Regulation Definition**

All equipment shall be operated and maintained according to manufacturers’ instructions.

**ST - P0902 - EQUIPMENT**

**Title** EQUIPMENT  
**Statute or Rule** 59A-6.022(5)(b) FAC  
**Type** Rule

**Regulation Definition**

Documentation of maintenance, daily function checks and instrument calibration performed in accordance with manufacturers’ instructions, shall be maintained for a minimum of two years. Documentation of the maintenance, daily function checks and instrument calibration procedures and the manufacturers’ instructions must be maintained by the center and available for review by the agency as required under Rule 59A-6.022, F.A.C.

**ST - P0903 - EQUIPMENT**

**Title** EQUIPMENT  
**Statute or Rule** 59A-6.022(5)(c) FAC  
**Type** Rule

**Regulation Definition**

Equipment shall be protected from fluctuations and interruptions in electrical current that adversely affect patient test results.
<table>
<thead>
<tr>
<th>Title</th>
<th>SANITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(4)(a) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The center or mobile facility shall be maintained in a clean and sanitary condition in compliance with Section 381.0098, F.S., and Chapter 10D-104, F.A.C.

<table>
<thead>
<tr>
<th>Title</th>
<th>SANITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(4)(b) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

Testing areas shall be well lighted and ventilated.

<table>
<thead>
<tr>
<th>Title</th>
<th>SANITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>59A-6.022(4)(c) FAC</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

**Regulation Definition**

Reusable items capable of transmitting infection from consumer to consumer shall be sterilized after each use consistent with paragraph 59A-6.022(30)(f), F.A.C. A schedule for resterilization of items of equipment shall be
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

established for those items that may transmit infection from consumer to consumer.

<table>
<thead>
<tr>
<th>ST - P2000 - PHYSICAL ENVIRONMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

*Regulation Definition*  
Testing areas shall be configured so as to ensure the privacy of the consumer being tested.

<table>
<thead>
<tr>
<th>ST - P2001 - PHYSICAL ENVIRONMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

*Regulation Definition*  
The center shall provide a functional, sanitary, and comfortable environment for consumers and staff.

<table>
<thead>
<tr>
<th>ST - P2002 - PHYSICAL ENVIRONMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

*Regulation Definition*  
The center must be configured and maintained to ensure the space, ventilation and utilities necessary for conducting all
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

phases of testing, as appropriate.

<table>
<thead>
<tr>
<th>ST - P3000 - PHYSICAL PLANT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

**Regulation Definition**

There shall be documentation that the center is in compliance with all applicable local, state, and federal building, fire and safety codes.

<table>
<thead>
<tr>
<th>ST - P3001 - PHYSICAL PLANT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

**Regulation Definition**

Mobile units shall be so designed as to accommodate all necessary equipment, provide privacy for the consumer, toilet facilities and lavatory with single service towels.

<table>
<thead>
<tr>
<th>ST - P4000 - ADVERTISING AND PROMOTIONAL MATERIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Statute or Rule</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
</tbody>
</table>

**Regulation Definition**

A center may not use advertisements or promotional materials
Aspen State Regulation Set: P 2.01 Multiphasic Health Testing Ctr

that tend to deceive prospective purchasers concerning the personnel, equipment, care, and services, or the quality thereof, provided by the center.

<table>
<thead>
<tr>
<th>Title</th>
<th>ADVERTISING AND PROMOTIONAL MATERIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statute or Rule</td>
<td>483.305(2) FS</td>
</tr>
<tr>
<td>Type</td>
<td>Rule</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each advertisement shall contain a statement in easily read type, no less in size than that used to list the tests, that reads as follows:</td>
<td></td>
</tr>
</tbody>
</table>

"Health screening tests may or may not alert you and your doctor to serious medical problems, and are not intended to be a substitute for a physician's examination." This statement shall be voiced in radio and television advertising; the statement shall also be prominently displayed on its report of the tests and in a place that is in clear and unobstructed public view within the center or mobile facility. The notice displayed within the center or mobile facility shall be made up of block letters not less than one inch in height that are clearly visible.