

Discussion of Current Regulation & Proposed Changes

Rule 59A-7.034

Hospital Alternative-Site Testing

presented to: First Coast Point of Care Group

State of Florida, Agency for Health Care Administration

Division of Health Quality Assurance

Bureau of Health Facility Regulation, Laboratory Unit

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Objectives

- Provide a brief history of Hospital Alternate-Site Testing regulation.
- Provide an overview of current regulatory requirements under section 59A-7.034, Florida Administrative Code (Hospital Alternate-Site Testing Rule).
<https://www.flrules.org/gateway/ChapterHome.asp?Chapter=59A-7>
- Discuss rule development underway for section 59A-7.034, Florida Administrative Code.
<https://www.flrules.org/gateway/result.asp>
- Provide listing of Agency contacts

Brief History of Clinical Laboratory Hospital Alternate-Site Testing Regulation Development

- Under section 483.051 (9), Florida Statutes, *Powers and duties of the agency*, the Agency is required to adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director.
- The statute was enacted in 1994 and the rule was developed and adopted in 1995.
- Fourteen years later, in 2009, the rule was amended for the first time to add EMS personnel to the list of staff able to perform alternate-site testing and a description of a “satellite laboratory” was added along with some technical changes to update regulatory references that had changed.

History, continued

- In 2010, clinical laboratory directors and other medical professionals at large Florida hospitals advised the Agency that under the existing regulation, state-of-the-art Point of Care testing equipment that promotes better patient care and recovery and that is currently available to residents of other states, could not be used in Florida hospitals. These professionals argued that existing regulation put patients at risk and required physicians to use methods that were not considered to be best practice and requested the Agency look at amending these regulations.
- The Agency held a public meeting in May of 2010 and after that meeting determined that rule development was required to address the advancement in clinical laboratory testing equipment for Point of Care testing in Florida hospitals.
- After holding a public rule workshop in August, the Agency developed new rule language based on public comment. If requested in writing, a public hearing is scheduled to be held on Rule 59A-7.034 on October 21, 2010 at 2:30 p.m. in the Agency's conference room D. Notice appeared in the September 24, 2010 edition of the [Florida Administrative Weekly](#).
- An Alternate-Site Testing web page has been developed that provides the most recent rule development activity at:
http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/altsite.shtml.

Overview of existing regulation of clinical laboratory alternate-site testing in hospitals

Section 483.051 (9), Florida Statutes contains the following language:

ALTERNATE-SITE TESTING.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to:

- a hospital internal needs assessment;
- a protocol of implementation including tests to be performed and who will perform the tests;
- criteria to be used in selecting the method of testing to be used for alternate-site testing;
- minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals;
- documented in-service training as well as initial and ongoing competency validation;
- an appropriate internal and external quality control protocol;
- an internal mechanism for identifying and tracking alternate-site testing by the central laboratory;
- and recordkeeping requirements.
- Alternate-site testing locations must register when the clinical laboratory applies to renew its license.

For purposes of this subsection, the term “alternate-site testing” means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

Overview, continued

- Rule 59A-7.034, Florida Administrative Code contains regulations that address each of the elements required by statute.
- Requirements for agency reporting are described under subsection (2) of this rule and under the state application and include:
 - A requirement to provide written notification to the Agency that specifies the categories of personnel testing.
 - In addition to a listing of all testing site locations, a copy of the most recent internal needs assessment that includes an evaluation of proposed methodologies for tests to be performed at the alternate-sites. The needs methodology must contain an evaluation of accuracy, precision, comparison of test results with the hospital laboratory, instrument performance, maintenance requirements, reagent preparation, if applicable, and storage and availability of supplies such as reagents, controls and proficiency samples for the testing site.

Overview, continued

- The Agency is directed by this rule under subsection 8 to take administrative action “*up to and including revocation of the approval for operation of any or all alternate-testing sites*” where the Agency determines that the site(s) have operated in violation of any of the provisions of Chapter 483, Part I, Florida Statutes or Rule 59A-7, Florida Administrative Code, which includes this rule.
- This subsection indicates that the Agency must approve the alternate-site.
- Recently the Agency has become aware that some hospitals had initiated alternate site testing prior to Agency approval. In a number of instances the testing performed or some other element of the alternate site did not meet the requirements of this rule. In these cases, the ability to do alternate-site testing was revoked until the hospital came into compliance.

Overview, continued

- To assist hospitals in understanding current regulations, the Agency created the Hospital Alternate-Site Testing web page at:
http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/altsite.shtml
- This web page lists instruments the Agency has reviewed as part of an existing hospital's submission for establishment of an alternate site and is not meant to list all Point of Care instruments available. Please note that a listing on this web page is not an endorsement of any test, analyte, procedure, or manufacturer.

Overview, continued

Can be performed at alternate site	Cannot be performed at alternate site	Can only be performed at alternate site under certain circumstances
Any Waived Instrument (All Waived Tests)	Any High Complexity Instrument (All High Complexity Tests)	Medtronic Hepcon HMS Plus Circumstances (click for circumstances)
Abbott-i-STAT Tests & Analytes (click for listing)	Any Provider Performed Microscopy Procedures Procedures (click for listing)	
ACT Tests & Analytes (click for listing)	Stratus® CS Tests & Analytes (Click for listing)	
IL Gem Premier 3000 Tests & Analytes (click for listing)	Amnisure Tests & Analytes (click for listing)	
IL Gem Premier 4000 Tests & Analytes (click for listing)	CMA 600 Microdialysis Tests & Analytes (click for listing)	
Accumetrics VerifyNow P2Y12 (Platelet Glycoprotine IIB/IIIA Receptor Blockade Analyte)	TEG® 5000 Series & TEG® 3000 Series Manufactured by Haemoscope aka Haemonetics® (Thromboelastograph Test)	

This is not an endorsement of any test, analyte, procedure, or manufacturer.

Snapshot of alternate-site web page with listing of tests.

Overview, continued

- Under current regulations, hospitals must submit notification to the Agency of any alternate-site testing.
- The Agency reviews all proposals to establish alternate-sites and either approves the proposal or notifies the hospital if there is a problem by describing why the proposal is not acceptable or, if it is incomplete, what additional information is needed for review.

Alternate-site rule development underway

- The Agency has published proposed rule language in the Florida Administrative Weekly.
http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/docs/altsitehearingoct2010.pdf.
- The Agency will listen to testimony presented at the public hearing, assuming one is requested and determine how to proceed.
- Unfortunately, we cannot predict the outcome of this process. There is no guarantee that proposed language shown in the next few slides will be adopted.

Highlights of some of the areas proposed to change

(4) ~~(3)~~ Hospital Internal Needs Assessment:

- (a) The laboratory director in consultation with the appropriate medical staff shall prepare an internal needs assessment for alternate-site testing. Each testing site assessment shall include an evaluation of patient benefits and criteria for such testing, location of alternate-site, population to be served, and an evaluation of proposed instruments or testing methodologies to determine if the requirements listed in subsections (8) through (12) are met .
- (b) The selection of alternate-site test methods shall assure that performance and operational characteristics meet the clinical requirements for the intended alternate-site testing location. The internal needs assessment shall include an evaluation of proposed methodologies for tests to be performed at the alternate-sites composed, at a minimum, of evaluation of accuracy, precision, comparison of test results with the hospital laboratory, instrument performance, maintenance requirements, reagent preparation, if applicable, storage and availability of supplies such as reagents, controls and proficiency samples for the testing site and a written validation procedure .
- (c) Alternate-site testing shall only be conducted at sites where the director has established and documented in the internal needs assessment that such testing is necessary for the proper care and treatment of patients.
- (d) The internal needs assessment must be reviewed and approved by the laboratory director prior to initiation of testing at any alternate-test site and biennially thereafter.
- (e) All records related to the internal needs assessment for the purpose of alternate-site testing must be readily available for inspection by the agency and any other surveying agency including accrediting organizations, if the laboratory is accredited, for a minimum of two years after testing is discontinued.

*underline signifies new language proposed

Highlights, continued

(5) Approval of Alternate-Site Testing:

(a) A request for approval of any new instrument or testing methodology not currently listed by the Agency's Internet site:

http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/altsiterule.shtml and incorporated herein by reference, as approved for alternate-site testing, must be submitted to the Agency for review and approval prior to implementation. If the instrument is listed as an unapproved test, then it cannot be performed at an alternative-site. If a test is listed as approved under specific circumstances, those circumstances must be met in order for the test to be performed.

(b) A request for approval of any new instrument or testing methodology must include the location of the alternate-site, category of personnel who will perform the tests, name of the instrument or method to be used, instrument manufacturer and model number if applicable, and any other information necessary for the Agency to determine whether tests to be performed meet the criteria established in subsection 10 .

(c) Requests must be sent to: Agency for Health Care Administration, Clinical Laboratory Unit, M.S. 32, 2727 Mahan Drive, Tallahassee, Florida 32308. The agency will respond with either a request for additional information or approval within 30 days of receipt of the request.

(d) Instruments or testing methodologies previously approved and listed on the Agency's alternate-site testing website at:

http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/altsiterule.shtml do not require prior approval.

(f) A listing of all alternate-site testing locations and laboratory tests performed at each site must be included with each laboratory license renewal application.

- *underline signifies new language proposed

Highlights, continued

- (10)(7) Tests Performed: ~~performed~~. Only test procedures approved by the agency laboratory director and documented in the internal needs assessment in accordance with Rule 59A-7.034, F.A.C., shall be performed at the alternate-test site.
- (a) Tests performed at these sites shall not exceed moderately complex test procedures and must:
1. Employ whole blood specimens that require no specimen or reagent manipulation, treatment, extraction, separation or any other processing of any kind by the operator; and
 2. Utilize automated test systems in which a specimen is directly introduced into the system. Such instrumentation shall automatically provide for instrument calibration without access by the operator to modify or adjust calibration limits. If the instrument has a requirement to establish quality control ranges, the ranges must be established by appropriately licensed clinical laboratory personnel.
- (b) Alternate-test sites are also permitted to perform waived tests, activated clotting times, gastric occult blood, gastric pH and urine specific gravity by refractometer. Heparin concentration, heparin assay, heparin dose response and thrombelastograph tests are permitted to be performed only by perfusionists certified by the American Board of Cardiovascular Perfusion or laboratory personnel licensed as director, supervisor, or technologist under Chapter 483, Part III, F.S.
- (c) Data output must be directly reportable in the final units of measurement needed for patient care without need for data conversion or other manipulation, with the exception of heparin concentration, heparin assay, heparin dose response and thrombelastograph tests, which shall be interpreted by the attending physician.
- (d) Electronic instrumentation must have a mechanism whereby the operator is alerted when patient results exceed the reportable operating range of the test method and when calibration is not acceptable; such results shall not be used for the diagnosis, treatment, management or monitoring of patients as required under Rule 59A-7.029, F.A.C., and shall be validated through the central laboratory.

*underline signifies new language proposed

Possible web page changes if proposed language is adopted

The proposed language published with the “Notice of Proposed Rule” in the Florida Administrative Weekly on September 24, 2010 if finally adopted would mean changes were needed to the Agency’s web site. Based on proposed language, the changes would be similar to those shown here and on the following slide.

Again, we cannot predict the outcome of rule development currently underway.

Hospital Alternate-Site Testing

483.051(9), Florida Statutes and 59A-7.034, Florida Administrative Code

The tests listed below are tests that have been reviewed and approved by the agency as tests that can be performed at a hospital alternate-site. If the test you wish to perform at the alternate-site is not listed as an approved test in the listing below, or has not otherwise been determined that it cannot be performed at an alternate-site, please contact the Agency consultant by checking the list on consultants and assigned areas of the state:
http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Laboratory_Licensure/maps.shtml

The following listing of tests is not an endorsement of any test, analyte, procedure or manufacturer.

APPROVED	NOT APPROVED	Can only be performed at alternate site under certain circumstances
Can be performed at alternate site Any Waived Instrument (All Waived Tests) Abbott-i-STAT Tests & Analytes (click for listing)	Cannot be performed at alternate site Any High Complexity Instrument (All High Complexity Tests) Any Provider Performed Microscopy Procedures Procedures (click for listing)	Medtronic Hepcon HMS Plus Tests & Analytes (Click for listing) Stratus® CS Tests & Analytes (Click for listing)
Activated Clotting Time (ACT) Tests & Analytes (click for listing)	Amnisure Tests & Analytes (click for listing)	TEG® 5000 Series & TEG® 3000 Series Manufactured by Haemoscope aka Haemonetics® (Thromboelastograph Test)
Accumetrics VerifyNow P2Y12 (Platelet Glycoprotein IIb/IIIa Receptor Blockade Analyte)	CMA 600 Microdialysis Tests & Analytes (click for listing)	
IL Gem Premier 3000 Tests & Analytes (click for listing)		
IL Gem Premier 4000 Tests & Analytes (click for listing)		

Possible web page changes if proposed language is adopted, continued

Stratus CS

Listing of tests that **can** be performed at a hospital alternate site as long as the control ranges are established by appropriately licensed clinical laboratory personnel.

Test System / Manufacturer	Analyte	Analyte Specialty	Complexity
Stratus © CS Acute Care TM Diagnostic System	C-Reactive Protein	General Immunology	MODERATE
Stratus © CS Acute Care TM Diagnostic System	Myoglobin	General Chemistry	MODERATE
Stratus © CS Acute Care TM Diagnostic System	Creatine Kinase MB Fraction (CKMB)	General Chemistry	MODERATE
Stratus © CS Acute Care TM Diagnostic System	Troponin-I (Cardiac)	General Chemistry	MODERATE
Stratus © CS Acute Care TM Diagnostic System	D-Dimer	Hematology	MODERATE
Stratus © CS Acute Care TM Diagnostic System	ProBNP (N-Terminal Pro Brain Natriuretic Peptide)	General Chemistry	MODERATE
Stratus © CS Acute Care TM Diagnostic System	hCG, Beta, Serum, Quantitative	Endocrinology	MODERATE

Medtronic Hepcon HMS Plus

Heparin Assay

NOTE: These tests may only be performed by perfusionists certified by American Board of Cardiovascular Perfusion and results must be interpreted by the attending physician.

Test System / Manufacturer	Analyte	Analyte Specialty	Complexity
Hepcon HMS Plus	Heparin Dose Response	Hematology	MODERATE
Hepcon HMS Plus	Heparin Assay	Hematology	MODERATE
Hepcon HMS Plus	Heparin Concentration	Hematology	MODERATE

 [\(return to alternate site page.\)](#)

Hospital Alternate-Site Testing

TEG© 5000 Series & TEG© 3000 Series
 Manufactured by Haemoscope aka Haemonetics©
 (Thromboelastograph Test)

NOTE: This test may only be performed by perfusionists certified by American Board of Cardiovascular Perfusion and results must be interpreted by the attending physician.

 [\(return to alternate site page.\)](#)

Hospital consultants

- Beginning this September, the Agency's Hospital & Outpatient Services Unit began reviewing hospital clinical laboratory licensure renewal applications that have been aligned with the hospital's license and any new applications to establish new laboratories and new hospitals .
- Hospitals are required by law to report alternate-sites on their renewal applications. However, if you have a new alternate-site location to report, the Clinical Laboratory Unit will continue to do alternate-site reviews for hospitals.
- If you have questions about hospital alternate site testing, please contact a consultant in the Clinical Laboratory Unit.

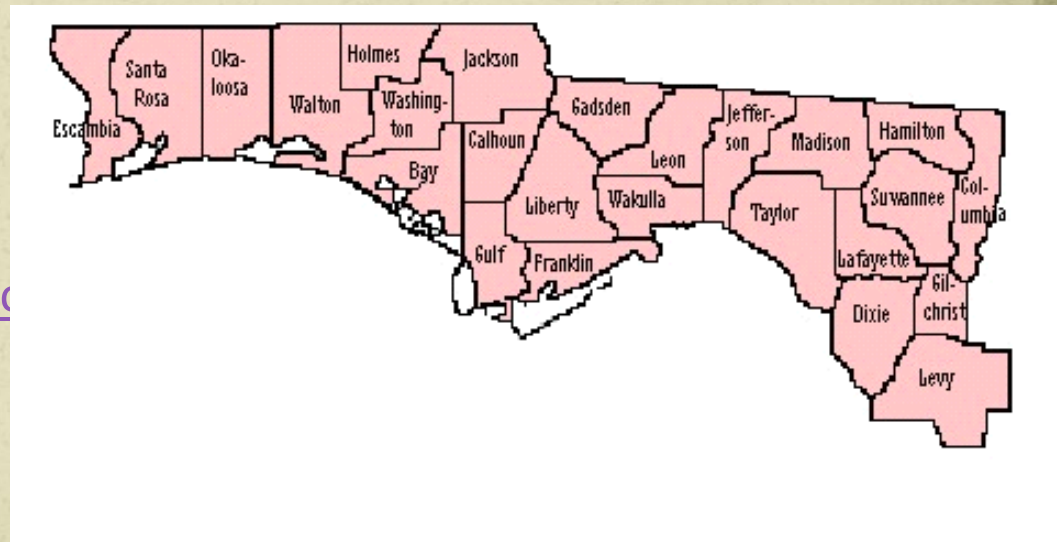
Clinical Laboratory Unit Contacts

- The state is divided in to review areas by counties. Consultants are assigned by area.

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/maps.shtml

Area 2 Contact

- Non-Waived laboratories:
Contact Janet Crain
(Janet.Crain@ahca.myflorida.com)



Clinical Laboratory Unit Contacts

Area 4 Contact

- Non-Waived laboratories:
Contact Mary-Imani Rutherford (Mary-Imani.Rutherford@ahca.myflorida.com)



Clinical Laboratory Unit Contacts

Area 5 Contact

- [Non-Waived laboratories](#)

Contact April Asbell (April.Asbell@ahca.myflorida.com)



Clinical Laboratory Unit Contacts

Area 7 Contact

- Non-Waived laboratories:

Contact Janet Crain (Janet.Crain@ahca.myflorida.com)



Clinical Laboratory Unit Contacts

Area 8 Contact

- Non-Waived laboratories:

Contact April Asbell (April.Asbell@ahca.myflorida.com)



Clinical Laboratory Unit Contacts

Area 11 Contacts

- Non-Waived laboratories:
Contact Cierra Glover
(Cierra.Glover@ahca.myflorida.com)



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