

# Alternate-site Testing

**October 30, 2011 Final Rule  
59A-7.034, Florida Administrative Code**

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# Speakers

- Dayle Mooney, Program Administrator  
Agency for Health Care Administration (AHCA)  
Laboratory Licensing Unit  
[Dayle.Mooney@ahca.myflorida.com](mailto:Dayle.Mooney@ahca.myflorida.com)
- Karen Rivera, Manager  
Agency for Health Care Administration (AHCA)  
Laboratory Licensing Unit  
[Karen.Rivera@ahca.myflorida.com](mailto:Karen.Rivera@ahca.myflorida.com)

(850) 412-4500



# Objectives

- Highlight changes to Rule 59A-7.034, Florida Administrative Code (FAC).
- Highlight what has not changed in Rule 59A-7.034 FAC.
- Provide listing of on-line resources for rule location.
- Question and answer period.

# Changes to Alternate-site Rule Related to Testing Performed

- Web site hosted by AHCA with listing of clinical laboratory tests that can and cannot be performed at hospital alternate-sites updated to remove listing of approved clinical laboratory tests.
  - Listing of approved alternate-site tests no longer incorporated in rule.
  - Only test procedures approved by the clinical laboratory director and documented in the internal needs assessment can be performed at the alternate-test site.

# Changes to Alternate-site Rule Related to Testing Performed

- Testing clarified to indicate that any testing that requires *manual* specimen or reagent manipulation, treatment, extraction, *centrifugation*, separation or any other processing of any kind by the operator *as determined by the clinical laboratory director* is not allowed.
- Testing no longer limited to “whole blood”.

# Changes to Alternate-site Rule Related to Testing Performed

- Moderately complex testing on bodily fluids such as amniotic fluid requiring minimal preparation may also be performed, as determined by the laboratory director.
- Changes related to testing are contained in subsection (9) of the amended rule.

# Changes to Alternate-site Rule Related to Personnel

- Only a perfusionist certified by the American Board of Cardiovascular Perfusion, *determined eligible for certification by the American Board of Cardiovascular Perfusion, or who has two years of clinical experience in cardiovascular perfusion with 100 clinical perfusions conducted as of January 1, 1981*, may perform testing.
- Changes related to personnel are contained in subsection (7) of the amended rule.

# Changes to Alternate-site Rule Related to Laboratory Director Responsibilities

- Directors now have discretion in determining which tests can be performed as long as they are within the guidelines sent out in this rule.
- Directors no longer need to obtain prior approval from AHCA before developing an alternate-site, including the determination of which tests to perform (as long as the testing falls within the rule guidelines in subsection 9).

# What has not changed at hospital alternate testing sites?

- Only waived and moderately complex testing may be performed.
- High complexity testing, including CLIA/FDA “unapproved” tests, cannot be performed.
- Director responsibilities for staffing, recordkeeping, protocols, quality assurance, internal needs assessment, test methods, supervision, staff competency, credentials, and training, and overall compliance with this rule, Chapter 483, Part I and Rule 59A-7 as they relate to alternate-sites remain the same.

# What has not changed at hospital alternate testing sites?

- Administrative action for violations of state statutes and rules at these alternative sites will be taken according to Sections 483.201, 483.221, 408.806, 408.813, 408.814, 408.816 and 483.23, F.S.
- Administrative action taken may be up to and including revocation of the laboratory license of the laboratory maintaining the alternate-site.
- Listing of alternate site locations must be included on hospital clinical laboratory licensure application.

# On-line Resources

- Applicable regulations:
  - Florida Statutes (F.S.): [www.leg.state.fl.us](http://www.leg.state.fl.us)
    - Chapter 483, Parts I and III, F.S.
    - Chapter 408, Part II, F.S.
  - Florida Administrative Code (FAC):  
<https://www.flrules.org/default.asp>
    - Rules 59A-7, 59A-35 and 64B3, FAC

# On-Line Resources

- AHCA Clinical Laboratory Unit:

<http://ahca.myflorida.com/labs>

- AHCA Alternate-site Website:

[http://ahca.myflorida.com/mchq/health\\_facility\\_regulation/laboratory\\_licensure/altsiterule.shtml](http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/altsiterule.shtml)

E-Mail:

– [LABSTAFF@ahca.myflorida.com](mailto:LABSTAFF@ahca.myflorida.com)

# Questions & Answers

*Thank you for inviting us and feel free to contact either of us.*

Dayle Mooney, Program Administrator  
Laboratory Licensing Unit  
[Dayle.Mooney@ahca.myflorida.com](mailto:Dayle.Mooney@ahca.myflorida.com)

Karen Rivera, Manager  
Laboratory Licensing Unit  
[Karen.Rivera@ahca.myflorida.com](mailto:Karen.Rivera@ahca.myflorida.com)

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