CLIA Corner

The University of Iowa Hygienic Laboratory

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In This Issue...

CLIA Clarification: Immunohematology Gel Crossmatch

In the July–August 2009 edition of the CLIA Network Newsletter, the issue of performing donor-recipient crossmatch testing using the gel test system was addressed. The letter clarified that to be in compliance with the CLIA regulations the laboratory must perform an immediate spin crossmatch or an electronic crossmatch, ***in addition*** to the gel testing crossmatch.

The CLIA regulation, 493.1271(a)(1), requires laboratories performing compatibility testing to follow the Food and Drug Administration (FDA) regulations, 21 CFR 606.151(a) through (e). At 21 CFR 606.151(c), the FDA requires laboratories to follow "*Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.*"

The gel card only detects incompatibility based on the IgG antibodies. It does not detect incompatibility based on IgM antibodies, which is important in determining ABO compatibility. Therefore, the use of the gel card alone is not adequate to demonstrate incompatibility between the donor's cell type and the recipient's serum type, and the laboratory must also perform an immediate spin or electronic crossmatch to determine ABO compatibility.

Frequently Asked Questions

Q#1: What type of proficiency testing must we enroll in if we are using Methicillin-Resistant Staphylococcus aureus (MRSA) media for screening patients?

A: If the laboratory is currently performing routine bacteriology testing and is enrolled in a comprehensive proficiency testing module, the module ***must*** include at least one (1) MRSA sample per year. If the module does not include an MRSA specimen, then the laboratory must enroll in an additional MRSA module. This module may contain less than five (5) specimens per challenge because the laboratory is already enrolled in the comprehensive module.

If the laboratory does <u>not</u> perform routine bacteriology testing, the laboratory must enroll in a proficiency testing module for MRSA screening that includes five (5) specimens per challenge.

<u>REMINDER:</u> MRSA agar is non-exempt media meaning the end user must perform quality control procedures, i.e., for each batch, shipment and/or lot number, the laboratory using the media must check for positive and negative selectivity using the appropriate organisms.

Q#2: Our laboratory would like to start performing synovial fluid crystal examinations. What must we do to be compliant with the CLIA regulations?

A: <u>Personnel:</u> Synovial fluid testing is considered *high complexity testing*, so the laboratory must have personnel qualified to perform high complexity testing. This would include laboratory director, clinical consultant, technical supervisor, general supervisor and testing personnel. Training and competency assessments (twice during the first year of testing and annually thereafter) must be performed and documented for all testing personnel (including physicians).

<u>Validation:</u> As with all new tests and test systems, including text book and microscopy procedures, the test method must be validated. The laboratory must verify the accuracy, precision, reportable range and reference range.

<u>Proficiency testing:</u> Synovial fluid crystal examination is a non-regulated analyte; therefore, the laboratory must verify the accuracy at least twice annually. This may be accomplished by either enrolling in proficiency testing or performing split sample analysis.

<u>Procedure:</u> The procedure must be signed and approved by the laboratory director.

Q#3: Our laboratory information system (LIS) stores our quality control graphs and summaries. Do we need to print a hard copy?

A: As long as the *<u>daily</u>* quality control results are retrievable from the LIS system, the laboratory does not need to print and keep a hard copy of the results. The laboratory is responsible for verifying that the LIS system is backed up routinely. In addition, as part of the quality assurance activities the laboratory should monitor that the results are indeed retrievable and accurate for a minimum of two years.

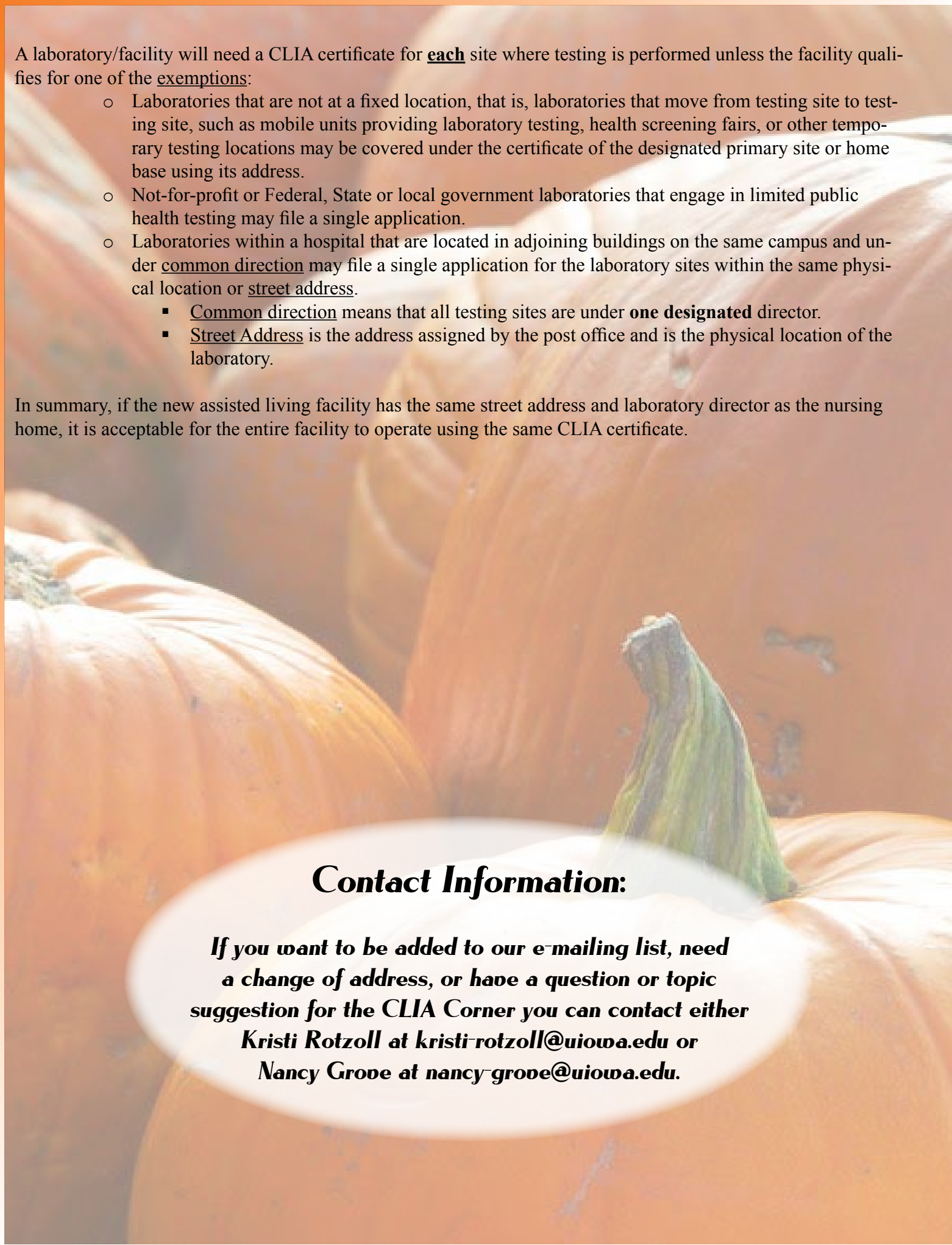
Q#4: We are a nursing and rehabilitation center that currently has a CLIA certificate of waiver in order to perform glucometer testing. We are in the process of building an assisted living facility which will be attached to our original building. Do we need a separate CLIA certificate for the new assisted living facility?

A: Under CLIA, a laboratory is defined as a facility that performs testing on material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. If the new assisted living facility intends to perform glucometer testing, and the nursing staff will be the individuals performing the testing, then the facility will need a CLIA certificate of waiver.

A laboratory/facility will need a CLIA certificate for **each** site where testing is performed unless the facility qualifies for one of the exemptions:

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing may file a single application.
- Laboratories within a hospital that are located in adjoining buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.
    - Common direction means that all testing sites are under **one designated** director.
    - Street Address is the address assigned by the post office and is the physical location of the laboratory.

In summary, if the new assisted living facility has the same street address and laboratory director as the nursing home, it is acceptable for the entire facility to operate using the same CLIA certificate.



Contact Information:

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