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To: Laboratories, COVID-19, and Serological (Antibody) Collection Sites

RE: Guidance for CLIA-approved high and moderate complexity laboratories to begin COVID-19 and Serological Testing

As the Kansas Department of Health and Environment (KDHE) continues to closely monitor an outbreak of the respiratory illness, coronavirus disease 2019 (COVID–19), the Kansas CLIA Department would like to review several requirements for facilities starting up the new testing of COVID-19. If your facility is sending samples for COVID-19 testing or serology samples to any facility except the KDHE State Laboratory, then please forward this information to their point of contact to ensure they are aware of the guidance. Many of the larger commercial laboratories are already aware and are following these guidelines.

Guidance for CLIA approved high and moderate complexity laboratories to begin COVID-19-2 and serological testing

1. Before beginning testing for COVID-19 or antibodies, you must inform the Kansas CLIA Department before patient testing can be done. Please include your facility name, CLIA Number, test system with manufacturer, estimated annual test volume and capacity in an email to KDHE.CLIA2@ks.gov.
2. COVID-19 is a reportable disease, so you must have a mechanism for reporting both positives and negatives to KDHE.
3. You must already be a CLIA-approved laboratory of compliance or accreditation.
4. All CLIA regulations should be implemented in the validation of COVID-19. Personnel qualified to perform the complexity indicated in the EUA of Kits being used (moderate or high complexity). Training of testing personnel and competency assessments, quality control regulations followed, validation of new test system (manufacturer's protocols, FDA, and CDC guidelines must be followed).
5. You must follow the FDA EUA approved Authorized Settings. For example, a facility holding a CLIA waiver cannot perform testing that has an Authorized setting of High (H) or Moderate (M). You must work within the scope of your CLIA certificate. The following is an excerpt of the FDA approval table to show what setting or complexity the test must be run within.

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]	Other Documents/
06/01/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay	Molecular	H	HCP, Patients, EUA Summary	None
05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Serology IgM and IgG	H, M	HCP, Recipients, IFU	None

6. If an approved EUA test system is being used, there cannot be any modification.
7. Submitting the first 5 negative and the first 5 positive specimens for confirmation to the KDHE Laboratory is no longer required. If laboratories choose to send samples to the KDHE Laboratory for validation, they may do so by submitting the sample as any other COVID-19 specimen.
8. Any laboratory developed tests (LDTs) must file for an EUA from the FDA within 15 days of starting patient testing if utilizing a test process not already granted an EUA.
9. Any laboratory developed tests (LDTs) should have the first 5 negative and the first 5 positive specimens forwarded to a public health laboratory performing the CDC EUA protocols for confirmation.

As always, the Kansas CLIA program is available to answer questions or provide assistance regarding this or other certification issues related to diagnostic patient testing. Send your questions to KDHE.CLIA2@ks.gov.

Recommendations from the FDA on the Use of Serological (Antibody) Tests for COVID-19:

- Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
- Be aware that not all marketed serological tests have been evaluated by the FDA. The FDA's authorized tests, including serological tests, are listed on the Emergency Use Authorization (EUA) page. Tests being offered under a policy outlined in the FDA's COVID-19 Diagnostic Policy Guidance are listed on our FAQ page. Tests without an EUA are classified as high complexity and cannot be performed in facilities and laboratories holding a CLIA Moderate Complexity or CLIA Waived Certificate.
- As of 7/31/20, no serological tests have been approved for testing under a CLIA Waived Certificate.

For more information on COVID-19 testing, visit:

FDA Emergency Use Authorizations
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

Information specific to Serological testing, visit:

CDC Interim Guidance for Coronavirus Disease (COVID-19) Antibody Testing

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Coronavirus (COVID-19) Update: FDA Provides Promised Transparency for Antibody Tests

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-promised-transparency-antibody-tests