Division of Environment
Curtis State Office Building
1000 SW Jackson St., Suite 400
Topeka, KS 66612-1367

Kansas Department of Health and Environment

Phone: 785-296-1535
Fax: 785-559-4264
www.kdheks.gov

Lee A. Norman, M.D., Secretary

Laura Kelly, Governor

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To: Laboratories and COVID-19 Collection Sites

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

1. Before beginning testing for COVID-19, you must inform the Kansas CLIA Department before patient testing can be done. Please include your hospital name and CLIA Number 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). If an approved EUA test system is being used, there cannot be any modification.
5. Depending on the protocol, you 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. You can continue to test patients while this is being done.
6. Please send the Kansas CLIA program the estimated annual volume of your planned testing capacity per the email above.
7. You 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.

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.