The 2019 novel coronavirus (SARS CoV-2) began its spread across central Iowa in mid-March, causing thousands of worried people to request immediate testing. Already, laboratories throughout the country were finding it extremely difficult to obtain much needed testing supplies, and MercyOne Des Moines Laboratory was no different. Early in the pandemic, much of the testing in place had not yet been developed or was simply unavailable as collection and test supplies were being directed to “hot spots” in other areas of the country. As fear and positive cases rose the FDA began to approve additional platforms and test kits, and manufacturer’s focused on increased production. Simultaneously, some of the constraints to testing set in place early on in the pandemic began to relax.

As MercyOne began to see increased COVID-positive cases throughout hospitals and Intensive Care Units, the MercyOne Medical Group-Central Iowa re-organized the East Village Family Medicine location to create the Fever and Upper Respiratory Infection (FURI) clinic, which provided the community with additional testing for patients exhibiting COVID-19 symptoms. However, numbers continued to increase and the FURI clinic care team quickly realized they were unable to support the patient loads experienced. Additionally, attempts to obtain timely results from national reference labs were unsuccessful, as these laboratories were overwhelmed with samples being sent from other testing sites. MercyOne was able to connect with a new opportunity through Corteva Agrisciences in Johnston, Iowa. Corteva’s team had a desire to apply their technical expertise in PCR molecular testing to testing for COVID-19 to assist the

**MercyOne Des Moines Expands COVID-19 PCR Testing**

CONTINUED ON PAGE 3
community in management of the public health event. Corteva had the expertise and MercyOne had the access to patients.

Following the first initial phone calls, a flurry of activity ensued, including legal and contractual work, technical validation studies, biosafety consultations, policy and procedure development, interface implementation, and CLIA certification. Expert teams from MercyOne and Corteva worked quickly to ensure the transition would be as smooth as possible, and by April 27, 2020 the first samples were referred to Corteva.

Corteva validated the COVID-19 testing using the ThermoFisher TaqPath™ RT-qPCR assay with samples obtained from a nasopharyngeal (NP) collection. This was the exact combination of instrumentation and reagents already approved as an FDA Emergency Use Authorization (EUA), which meant no further approvals from the FDA were necessary. Workflows were refined but supply challenges still arose, including finding sufficient numbers of NP swabs and collection vials, as these were still in short supply nationally.

In early May MercyOne Des Moines Laboratory was presented with Corteva’s objective to move to a method that didn’t rely on conventional collection materials and enhance the collection. The intent to validate saliva specimens, the science behind this approach, and a review of current literature was included. Upon mutual agreement to move to this next step, MercyOne obtained samples for the correlation studies necessary to establish and confirm acceptable performance characteristics of the TaqPath™ kits with the use of saliva. Data obtained from concurrent collections of NP swabs and saliva indicated saliva was as good or potentially a better sample type than NP swabs and collection vials, as these were still in short supply nationally.

In early May MercyOne Des Moines Laboratory was presented with Corteva’s objective to move to a method that didn’t rely on conventional collection materials and enhance the collection. The intent to validate saliva specimens, the science behind this approach, and a review of current literature was included. Upon mutual agreement to move to this next step, MercyOne obtained samples for the correlation studies necessary to establish and confirm acceptable performance characteristics of the TaqPath™ kits with the use of saliva. Data obtained from concurrent collections of NP swabs and saliva indicated saliva was as good or potentially a better sample type than NP swabs. On May 27, 2020, MercyOne began referring saliva samples to Corteva for testing.

Similar to the NP swab TaqPath™ method, the sensitivity of the saliva based TaqPath™ is a limit of detection (LoD) of 1,000 copies per ml. There is a 95% positive and negative concordance between NP swab and saliva samples. The specificity of this assay is 100%.

Even today, the MercyOne/Corteva COVID-19 PCR testing remains a relatively new workflow for both laboratories and work continues to optimize specimen collections, courier logistics, and result reporting. This partnership has enabled MercyOne to significantly increase access to COVID-19 patient testing to support pre-surgical/pre-procedural screening and larger scale surveillance activities.
MercyOne Des Moines Laboratory offers numerous tests to diagnose diarrhea, which may be caused by a number of organisms including bacteria, viruses, and parasites. Collection containers differ, depending on the test(s) ordered. Please review the information below and look in our test catalog for more information.

**Stool Culture**

Includes a routine culture which checks for Salmonella, Shigella, Aeromonas, and Shiga Toxin producing E. coli strains 1 and 2. Also included is a test for Campylobacter Antigen. If Yersinia or Vibrio are suspected organisms, Yersina Culture and Vibrio Culture should be ordered separately. Collection requirement for Yersinia and Vibrio is the same as for stool culture. One Orange Cap Cary Blair container is sufficient for a stool culture, Yersinia culture, and Vibrio culture. Swabs and formed stools are not acceptable for a Stool Culture.

**Collection Container:** Orange Cap Cary Blair

Stool sample must be placed in preservative within 2 hours of collection. Add stool specimen to orange cap container until level with preservative reaches the red line. Do not overfill. Once in the preservative, the sample is stable for 72 hours refrigerated.

**GI Panel by PCR**

Includes PCR testing for 22 bacteria, viruses, and parasites.

**Collection Containers:** Orange Cap Cary Blair AND Sterile specimen cup.

Add stool specimen to orange cap container until level with preservative reaches the red line. Do not overfill. Add 1ml stool specimen to an unpreserved sterile container. The unpreserved sample is needed for a reflex C difficile toxin test to be run if the C difficile PCR test is positive.

**Ova and Parasite Basic**

Includes Giardia antigen and Cryptosporidium antigen.

**Collection Container:** Black Cap Total Fix

Stool sample must be placed in preservative within 2 hours of collection. Add stool specimen to black cap container until level with preservative reaches the black line. Do not overfill. Once in the preservative, samples are stable for 2 months refrigerated.

**If results of the Ova and Parasite Basic are negative and want to reflex to Ova and Parasites-Concentrate and Smear, remember to collect both vials, the Black Cap Total Fix and the Green Cap EcoFix**

**Ova and Parasites-Concentrate and Smear**

Includes microscopic examination of concentrated stool specimen and trichrome stain and is sent out to Mayo Medical Laboratory. This test is only recommended if the patient has residence in or has recently traveled to a developing country, or if the patient has undiagnosed diarrhea and O & P Basic, Stool culture, C difficile toxin, and Rotavirus (in children) are negative. Turnaround time is 3-5 business days. Please consider ordering the O&P Basic first, as it covers the most common parasites found in Iowa, including Cryptosporidia which is not always detectable in the Ova and Parasites-Concentrate and Smear test. If Cyclospora is suspected, it needs to be ordered as a miscellaneous test and comment “Stool for Cyclospora stain to SHL”.

**Collection Container:** Green Cap EcoFix transport vial.

Stool sample must be placed in preservative within 2 hours of collection. Add stool specimen to green cap container until level with preservative reaches the green line. Do not overfill. Once in the preservative, samples are stable for 21 days at room temperature or refrigerated.
MercyOne Des Moines Laboratory Quality Scorecard

MercyOne Des Moines Laboratory is committed to improving the Quality of our services. In order to support our reputation as the premier laboratory in Central Iowa, we continually work on improving our processes. Here are some key observations from our 2019 4th Quarter Quality Scorecard:

- Specimen and Patient identification errors tied for the lowest number for a quarter (3 errors) in the past 4 years.

- Blood culture contamination for specimens collected by our lab staff has been below the target of 2.0% for 1 ½ years. Blood cultures are the most direct method for detecting bacteremia in patients. Interpretation of blood culture results may be complicated by recovery of bacteria that are potential contaminants. Patients with a false positive blood culture result have a significantly longer length of stay, and higher hospital costs than those with a negative blood culture result. MercyOne Des Moines Laboratory staff have focused on reducing blood culture contamination by increasing education for our phlebotomy staff. Phlebotomists with higher rates of contamination are evaluated by their supervisor utilizing a demonstration on a patient or phlebotomy arm to ensure proper technique. Newly hired staff also receive enhanced education. With these measures in place we have significantly reduced our contamination rate and successfully maintained it below the target.

- Patient satisfaction scores from our Outreach Patient Service Centers are 4.85 (on a scale of 5.0) and had 93 patients submit surveys. Our experienced, caring phlebotomy staff are an important part of the laboratory team. They will properly collect and stabilize all samples before sending them to our laboratory for testing.

Which Laboratory Test to Order?

Proper laboratory test order decisions should be based on clinical picture, clinical history, and evidence based practices. Our laboratory staff can help with locating specific tests in our test catalog (or from our approved reference laboratories); however, the test order choice must come from the provider. If clinical laboratory consultation is needed, our team of pathologists are available for guidance in selecting the "right test at the right time". They can be reached at 515-643-2870 or via PerfectServe.

Clinical follow up on laboratory results should come from the ordering provider. Laboratory staff cannot provide guidelines on how to treat a patient with a positive result.

Laboratory Patient Service Centers

MercyOne Des Moines Laboratory draw stations provide prompt, quality service at the locations listed below. For a basic blood draw, please utilize one of our three conveniently located patient service centers.

MercyOne Des Moines Health Plaza
411 Laurel St., Level A,
Ste. 265, Des Moines
P 515-643-8924  F 515-643-8239
Mon.-Fri., 7 a.m.-5 p.m.

MercyOne Clive Health Plaza
1601 NW 114th St., Ste. 134, Clive
P 515-222-7500  F 515-222-7510
Mon.-Fri., 7 a.m.-5 p.m.

MercyOne Ankeny Health Plaza
800 E. First St., Ste. 1400, Ankeny
P 515-643-7710  F 515-643-8176
Mon.-Fri., 7 a.m.-5 p.m.