Cordant Health Solutions™

Response to Clarification Request from:

State of Indiana, Department of Administration/
Department of Child Services for
Drug Testing Supplies and Services
RFP #21-2133

Due:

October 23, 2020, 12:00 p.m. Eastern

Submitted by:

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Respondent Clarifications

Technical Proposal

Section 6, Collection Management

1. What types of universal health and safety precautions for collection are you practicing?

Since the onset of the COVID-19 pandemic earlier this year, Cordant has implemented a number of procedures to ensure that our employees and clients stay safe as we continue to provide services. Even during many of the "stay-at-home" orders that were implemented throughout the country, our services were deemed to be an essential service. As such, Cordant immediately implemented the recommendations issued by the CDC including use of personal protective equipment (PPE), enhanced cleaning procedures, etc. Cordant stays abreast of the guidelines issued by the CDC and other state and local authorities and modifies procedures accordingly. Please see **Appendix A – Best Practice to Decrease Spread of Disease** as an example of the guidance we have released to all of our employees that are performing specimen collection services.

In addition, we revised our collection procedures to support social distancing and to limit the collector interaction with supplies and specimens during the collection process. See **Appendix B and C** for our COVID-19 touchless collection procedures for oral fluid collections and urine collections, respectively.

We also offer an innovative video-observed oral fluid collection process, which has helped many of our customers continue testing participants during the COVID pandemic. Oral fluid collections can be observed by a remote Cordant employee, a subcontracted collection site or by DCS staff, offering an innovative approach for alternative, rural, home-bound participants and emergency collections. This is a live video collection where the test vial and swab are on screen for the entire collection process, including the placement of the tamper seal, bagging of the specimen and preparation for shipment. Collection supplies can be sent directly to the participants homes with a pre-paid return mailer kit for delivery directly to the lab. During these times of required physical distancing, this method of collection has become increasingly popular to allow for continued testing and in preparation for any future emergency shutdowns. There is a tremendous amount of flexibility available with this approach, and we would be happy to discuss this option further with the DCS.

As required in the Scope of Work, Cordant will utilize subcontracted collection sites for a large portion of the collection services. In identifying partners, not only is the ability to properly provide quality services in an efficient, professional and empathetic way, but also in complete accordance with current health and safety guidelines. Prior to contracting with a site, we will review the health and safety guidelines in place at each site to ensure that they meet our minimum requirements. Further, Cordant reviews all training curriculum with the designated representative at each site to determine what training topics may not otherwise be included in their own employee training requirements. Cordant will ensure that all sites are performing collections in accordance the protocols that are mutually agreed upon by Cordant and Indiana DCS.

Cordant is committed to ensuring a safe environment for our clients, our collectors and collection partners. We intend to partner with the DCS during our initial implementation meetings to ensure we are in agreement with all health and safety precautions required and that they are implemented properly throughout the state.

2. *If you currently or have previously utilized subcontractors in any similar contract(s), please detail the measures you have taken to ensure quality. What is your plan to track accountability and to audit the performance of your proposed subcontractors?*

The DCS will have a full-time dedicated account manager to ensure the quality of this service offering. This dedicated resource will be responsible for periodic visits and audits for each collection site to review DCS protocols and requirements. Random site inspections are completed to ensure the protocols and requirements are strictly followed and in accordance with our expectations. An audit checklist will be developed during account implementation that includes all requirements of our subcontracted collection sites. During the course of the contract, this checklist will be completed and maintained for all site inspections performed. An example an audit checklist is included in **Appendix D**.

Like so many of the quality systems designed for the laboratory, the ability to monitor and document a robust program is built into all levels of the operation and sustained by continuous communication between Client Services, Operations and Quality leaders and the Laboratory Director.

One of the most important factors in evaluating collection subcontractor performance in a criminal justice program is their compliance with the vitally important chain of custody procedures. A ***quality drug test*** begins by following all the steps necessary to perform a proper specimen collection and completion of the chain of custody form. We will run collection error reports monthly and contact the appropriate facility to review the collection issues and proper collection protocol. When working with subcontracted collection sites, this is an important part of the process. Review of collection site errors and other issues with each specific site is undertaken by the Field Operations team on a periodic basis. Upon receipt of every specimen at Cordant's Laboratory, we record any potential error or fault with the specimen. Such errors or faults include, but are not limited to, the following:

- No collector signature on COC
- No donor signature on COC
- No donor initials on the security seal
- No seal over specimen lid
- Duplicate COC
- COC signature/donor name mismatch

Cordant will calculate an error rate for the site by calculating the total number of errors divided by the total number of collections performed in the same time period. Cordant then benchmarks this error rate against other collection sites in the State. If a site has an unacceptable error rate, Cordant will contact the site to discuss the errors and perform retraining. While this reporting is typically provided to the individual site, Cordant can provide error reporting to the DCS as well. The below figures represent sample reporting used to track accountability for chain of custody

errors in the collection process. These reports will be used to audit collection site effectiveness and allow for immediate intervention if the quality of services degrades. In **Figure 1** collection site errors can be evaluated month over month to address specific trends and allow for prompt corrective action. **Figure 2** reporting will provide an overall collection site summary error rate to evaluate general site effectiveness. **Figure 3** allows us to drill down each error to the sample level so we can work with the subcontractor to correct actions at the location, per each individual collector, error type and date.

Figure 1: Collection Site Total Deficiencies,

Deficiencies	JAN		FEB		MAR	
No COLLECTOR Signature on COC	3013	44.9%	2539	43.6%	2202	41.2%
No Donor SIGNATURE on COC	1759	26.2%	1553	26.6%	1519	28.4%
No Donor INITIALS on SEAL	937	14.0%	768	13.2%	575	10.8%
DUPLICATE COC#	396	5.9%	438	7.5%	379	7.1%
No ID on Specimen	194	2.9%	253	4.3%	274	5.1%
Specimen SEAL Not Intact	180	2.7%	148	2.5%	256	4.8%
No SEAL Over Specimen Lid	91	1.4%	69	1.2%	88	1.6%
Mismatched COC/Seal Numbers	46	0.7%	42	0.7%	45	0.8%
COC Signature/Donor Name Mismatch	95	1.4%	20	0.3%	2	0.04%
Total Deficiencies	**6711**		**5830**		**5340**	

Figure 2: Summary Collection Site Error Report,

Collection Site Name	Collection Site ID	Volume	Errors	Error %
Collection Site ABC		25	0	0.00%
Collection Site DEF		53	4	7.55%
Collection Site GHI		85	1	1.18%
Collectioon site JKL		85	1	1.18%
Collection Site MNO		4	0	0.00%
Collection Site PQR		67	3	4.48%
Collection Site STU		43	1	2.33%
Collection Site VWX		10	0	0.00%
Collection Site YZ1		124	4	3.23%
Collection Site Overall Error Totals		**574**	**19**	**3.31%**

Figure 3: High Detail Collection Errors by Location,

Collection Fault High Detail Report
Date Range: 10/01/2019 to 10/31/2019

Accession	COC	Code	Ordered	Client	Group	Description	
Client: 12345 Collection Site 1						**Total Errors:**	4
Date: 2019/10/02						Subtotal:	2
sample 1	xxx	2.1	10/2/2019	12345	fault	No Donor SIGNATURE on COC	
sample 2	xxx	2	10/2/2019	12345	fault	No Donor INITIALS on SEAL	
Date: 2019/10/04						Subtotal:	1
sample 3	xxx	2.1	10/4/2019	12345	fault	No Donor SIGNATURE on COC	
Date: 2019/10/11						Subtotal:	1
sample 4	xxx	2.2	10/11/2019	12345	fault	No COLLECTOR Signature on COC	

3. *In Question 12 of the Technical Proposal, the State asks Respondents about performance measures and corrective actions. In addition to corrective actions, please indicate if you or any of your subcontractors have experienced any the following issues in the past 12 months:*

   - *Termination of the entire contract or portions of the contract*
   - *Performance issues or deficiencies in service delivery*
   - *Involvement in contract disputes*

   Please describe all issues that fall into the above categories, and describe how you remedied the identified issues, if applicable.

Termination of Contracts

Cordant has not had any contracts terminated for cause. However, Cordant has had one contract terminated in the past 12 months under the "termination for convenience" clause. The termination for convenience notice was delivered during the height of the COVID-19 pandemic when no testing was being conducted on the clients' participant population.

Performance Issues or Deficiencies

Cordant has not experienced any significant issues providing services to clients.

Cordant takes pride in delivering an exceptional level of service to our clients. Our most recent customer survey results demonstrate a high satisfaction level by our clients. However, it should be noted that in the normal course of business, minor issues and challenges will crop up.

Cordant takes all issues, no matter how minor, very seriously. We work closely with our clients to truly understand the issues, identify the root cause, and make corrections to our processes to prevent the same issues from arising in the future. If the DCS has any issues or complaints, we ask that they contact Client Services and/or their Account Manager. Client Services and/or the Account Manager can resolve the majority of issues that arise. In the event issues need to be escalated further, the following Cordant leadership team can be contacted:

- Associate Vice President of Client Services
- Vice President and General Manager
- Executive Vice President

Involvement in Contract Disputes

Cordant has not been involved in any contract disputes.

Information Related to Subcontractors

Given the number of collection sites required throughout the State of Indiana, contacting all potential subcontractors was not practicable. However, WorkComp Management Services (WCMS) is our primary subcontractor for collection services and is providing a large majority of the sites required throughout the State. Per April Kaufman, Clinic Office Manager for WorkComp Management Services, Cordant notes the information below.

In the last 12 months:

- WCMS has not had any contract terminations
- WCMS has not had any performance issues or deficiencies in service delivery
- WCMS has not been involved in any contract disputes

Section 7, Staffing Requirements

1. *In your proposal, you state that "Cordant will support 200 court appearances per year." This RFP does not allow limits to be placed on court appearances, and requires the vendor to complete all requested court appearances regardless of quantity. Please confirm your understanding of this requirement.*

Cordant can support the litigation support requirements for the State of Indiana, Department of Child Services. In accordance with the requirements of the RFP, the cost of litigation support services was to be included as a “bundled” price for the drug testing services. As such, our pricing was built based on the estimates provided in the RFP, including the estimate of 200 court appearances per year.

Cordant confirms that we will support court appearances in excess of 200 per year. Upon request, we can provide pricing for our litigation support services if the requested services are in excess of the estimates provided in the RFP.

Section 14, Reports

1. *Please describe your proposed reporting of your quality control efforts during the course of this potential contract.*

Cordant believes there are three critical components of quality control in drug testing services, pre-analytical, analytical and post-analytical. Cordant tracks several collection and laboratory related metrics to ensure we meet our internal quality control goals as well as client expectations. For example, achieving our goals for turnaround time is a Cordant standard and absolute expectation. This is one of several key quality indicators monitored weekly to ensure customer satisfaction and allow for better outcomes through quick intervention. Pre-analytical quality metrics includes collection, supply and delivery tracking.
Analytical quality management focuses on the ability to detect significant clerical and analytical error before reporting results. Post-analytical quality management includes customer satisfaction, compliance and turn-around-time monitoring.

Cordant is committed to the success of your program and those successes will be communicated to the DCS for the quality of our entire offering as well as assurance to Performance Measures described in section 17 in the required scope of services. The below describe our proposed reporting of quality control efforts to the DCS.

Collection quality control. A quality drug test begins by following all the steps necessary to perform a proper specimen collection and completion of the chain of custody form. As mentioned above in **Question 2** quality metrics around proper collection are imperative and provide guidance around areas of improvement. Collection error reports are run on a monthly basis and provided to every collection facility . Please see question 2 above for a more comprehensive description of the quality control efforts and reporting process around collection services, including the collection site total deficiencies report that will be delivered to the DCS on a monthly or quarterly basis, or other agreed upon time frame.

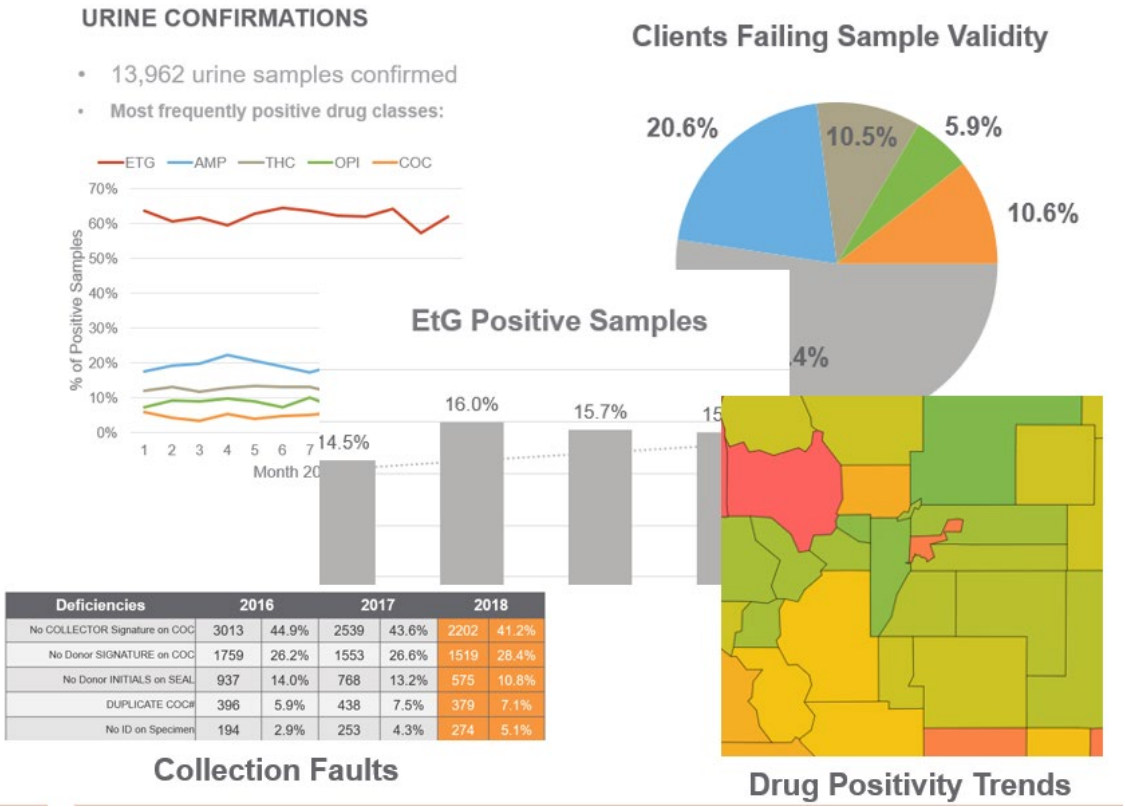
Laboratory quality control. The second important area of quality control is in testing performed in the laboratory. It is our continued certification through independently reviewing accrediting bodies that is evidence of the robustness of our internal quality control laboratory program. A CAP-FDT forensic certification is notable because it demonstrates the laboratory has to meet and maintain certain performance standards in order to be certified. CAP-FDT certification includes biennial onsite inspections by peer laboratories within our industry. These rigorous inspections audit every facet of the laboratory process including, but not limited to, equipment maintenance, testing validations, quality control, standards and reagents preparations, health and safety, laboratory and results security, chain of custody, lab director review processes, proficiency testing, staff qualification and training, and litigation processes. The quality of the results produced are continuously monitored by proficiency testing (PT) CAP program sets. The laboratory has never failed a PT event or an inspection. Cordant will deliver our updated certifications to the DCS as these inspections occur.

Reporting on Performance Measures. Per section 14 (Reports) in the scope of services document, Cordant will provide reporting on all required data points, including; number of

individuals tested, tests administered, substances detected, and number of individuals tested including location of test collection. As mentioned above, we will also report on testing not processed due to chain-of-custody issues during the collection process. Another critical interest to our clients are metrics on invalid, adulterated and/or substituted specimens. These standard reporting options will be delivered to the DCS on a monthly, quarterly and/or annual basis. The reporting interval will be established between Cordant and the DCS during implementation. Further, we will provide all reports summarized in our Technical Proposal necessary to satisfy the 10 performance measures.

In addition to the reporting outlined above and in our Technical Proposal, Cordant will provide a statewide Comprehensive Review for the DCS that will incorporate all of the above listed requirements, report and track the ability to meet the required performance measures, and can include any number of other specific ad-hoc reporting. A significant amount of data will be brought together to provide information on testing and collection services, at both the State level as well as the collection level. During the length of the contract we will be able to provide both an annual review, as well as year over year comparisons. Some of the data reviewed could include, but is not limited to; collection faults, drug testing panel utilization breakdown, drug class testing utilization, sample validity data overview, positivity distribution across screening and confirmation results, year over year sample testing volume analysis, district trends, client testing frequencies and client durations in program. This provides the DCS the ability to review their drug testing program effectiveness, better identify places for cost savings and understand drug usage trends across the state. Cordant will work closely with the DCS to incorporate all data points of interest as well as agreed upon time frames for review and mode of delivery. Please see below **Figure 4** for an example of just some of the data that will be incorporated into the Indiana DCS Comprehensive Review.

Figure 4: Statewide Comprehensive Review



Cost Proposal

1. *In your Attachment E: Cost Proposal, you did not enter prices for the following items. Please confirm that these items are offered at no cost:*

   In Table 4: Laboratory Analysis, 10-Panel: Confirmation testing for blood tests.
   In Table 5, Laboratory Analysis, Ad-Hoc: Confirmation testing for alcohol, methadone, and phencyclidine blood tests.

Cordant confirms that we can provide test results for all the substances included in the 10-drug panel and the ad-hoc testing substances in blood specimens. Cordant will perform the testing in blood utilizing *whole blood samples*, for which only direct-to-confirmation tests are utilized. Every blood toxicology result will be a confirmed quantitative result via LCMSMS. Our pricing for this direct-to-confirmation testing is included on the "Initial Level" line items in the Cost Proposal. Cordant confirms that no other fees will be incurred for blood testing.

Appendix A:

Best Practice to Decrease Spread of Disease

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BEST PRACTICES TO DECREASE SPREAD OF DISEASE (SAMPLE)

Cordant Health Solutions maintains universal precautions. Below are best practices to be followed.

- Establish a clearly defined “clean” area and “dirty” area
  - These areas can be labeled to indicate use, such as a sign saying “please place specimen here”
- Unused supplies, paperwork, your pen should be kept in the “clean” areas only
  - Any paperwork you are completing should be done in a clean area only
- Items that patients’ have used should be kept in “dirty” areas only
  - Paperwork being completed by a patient/donor should be kept in the “dirty” area only and placed by the patient directly into the specimen bag
- Specimens should be placed directly in a specimen tray
  - Recommended: contact free collections- the patient/donor is labeling and bagging any specimens
- Remove gloves after completing a collection and before touching any “clean” items such as your pen*

**Wearing gloves does not prevent the need for good handwashing or use of hand sanitizer. Hands should be washed/sanitized, and gloves changed between each collection.*

HAND WASHING

- Wet your hands with clean, running water and apply soap
- Scrub the backs and fronts of your hands, between fingers and under your nails for at least 20 seconds. Need a timer? Hum the “Happy Birthday” song from beginning to end twice.
- Rinse your hands well under clean and running water
- Dry your hands using a clean towel or air dry them

USING HAND SANITIZER

- Apply the gel product to the palm of one hand (read the label to learn the correct amount)
- Rub your hands together
- Rub the gel over all the surfaces of your hands and fingers until your hands are dry. This should take around 20 seconds

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CLEANING BETWEEN PATIENTS

- While wearing gloves, wipe down the designated “dirty” area using cleaning supplies
- Make sure you order cleaning supplies well in advance if you are running low
- Clean items or surfaces touched by the patient/donor
- Remove gloves
- Wash hands or use hand sanitizer.

GENERAL CLEANING

At the end of each shift, or if something “dirty” is placed in your designated “clean” area, clean the area using disinfectant cleaning supplies.

Disinfectant cleaning supplies can include:

- Alcohol wipes (60% alcohol)
- Bleach solution
- Disinfectant wipes
- Disinfecting cleaning solution (i.e. Lysol, Clorox etc.)

The following are not disinfecting:

- Glass cleaner
- Multi-surface cleaners that don’t specify disinfectant on the label

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Using/Removing

- If using a mask, the mask should be put on prior to putting on gloves. Then, apply gloves.
- Once gloves are used, ensure you are not making any adjustments to your facemask or touching your face
- Removing gloves
    - Grasp the outside edge near the wrist
    - Peel the glove away from the hand, turning the glove inside out. Hold it in the opposite gloved hand
    - Slide an ungloved finger under the wrist of the remaining glove, then peel it off from the inside, creating a “bag” for both used gloves
    - Discard in designated receptacle*

**Remember to perform hand hygiene after using and discarding PPE*


1
Pinch and hold the **outside** of the glove near the wrist area.
2
Peel downwards, away from the wrist, turning the glove inside-out.
3
Pull the glove away until it is removed from the hand, holding the inside-out glove with the gloved hand.
4
With your un-gloved hand, slide your finger/s under the wrist of the remaining glove. **Do not touch** the outer surface of the glove.
5
Peel downwards, away from the wrist, turning the glove inside out.
6
Continue to pull the glove down and over the inside-out glove being held in your gloved hand.

Appendix B:

COVID-19 Touchless Collection of Oral Fluid Specimens

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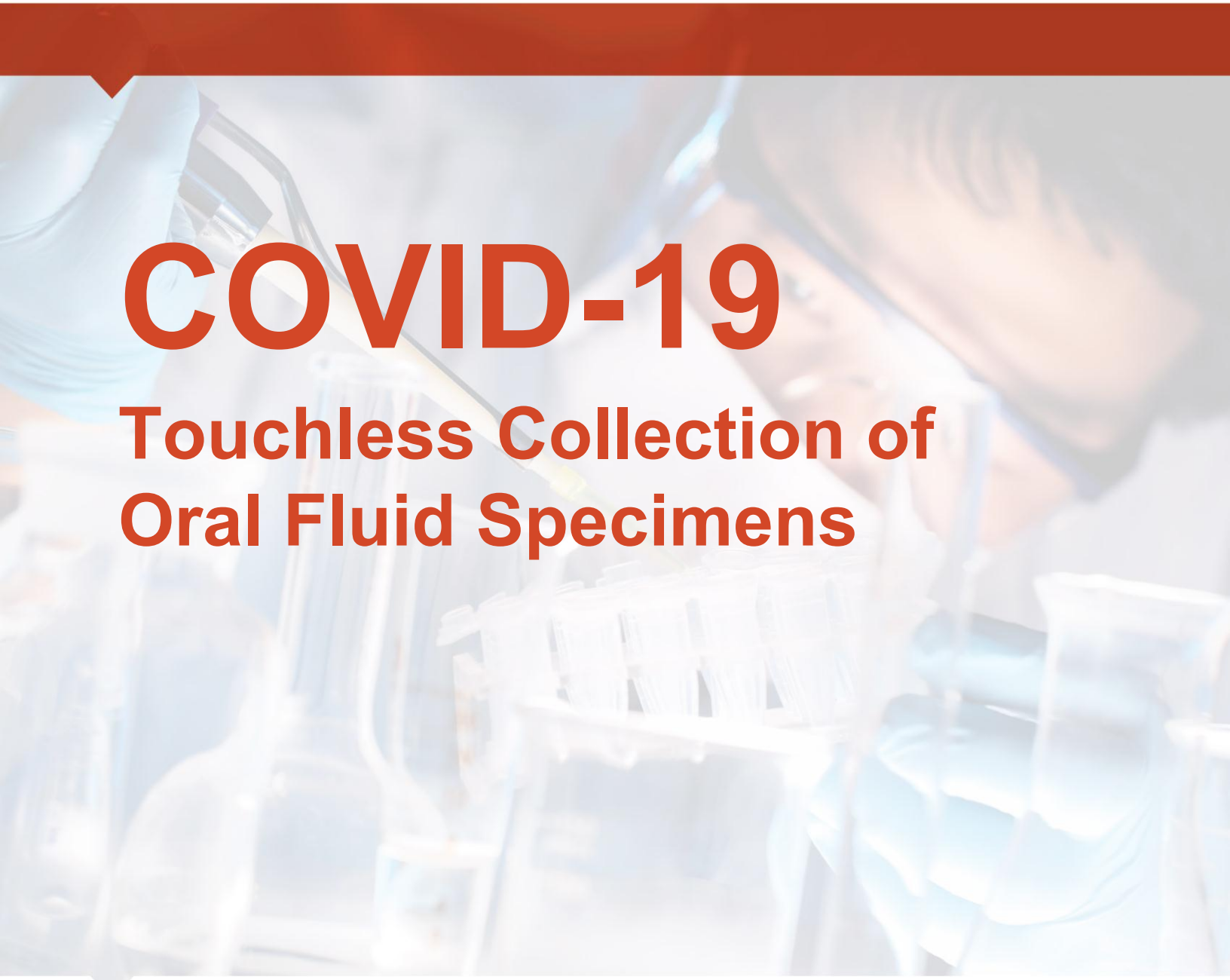
COVID-19

Touchless Collection of Oral Fluid Specimens



Approved by Dr. Damon Borg

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COVID-19 TOUCHLESS ORAL FLUID COLLECTION PROCEDURE

IMPORTANT POINT

The Collector and the Client shall keep the oral fluid specimen in view at all times prior to it being sealed with the provided tamper-evident seal. The working space should be accessible to both Client and Collector while **maintaining a distance of 6 feet from the workspace**. When each person is operating in the workspace, both should **maintain a distance of 6 feet from each other** so they are not sharing the space at any one moment.

Cordant recommends ***not*** proceeding with the collection if the client is visibly sick (sneezing, coughing, etc.).

COLLECTION OVERVIEW

1. Explain the process to the Client.
2. Ensure the Client has not had anything to eat, drink or smoke in the 10 minutes prior to collection.
3. Inform the Client if there is any significant discoloration of the specimen, it will be discarded and recollected.
4. Check the expiration date on the collection device.
5. Observe the entire collection process.
6. Collector is not to handle the collection device once the collection is complete.

COLLECTION

1. All work surfaces, including pens, should be sprayed and wiped down in between every collection USING 10% bleach disinfecting solution (1 part bleach to 9 parts water). Allow surface to completely dry. Collector and Client must wear gloves at all times.
2. Have Client pull up sleeves to ascertain that they are not hiding anything. Have Client wash their hands thoroughly with copious amounts of water to thwart attempts to conceal items on or around the hands and arms. Have Client place on gloves.
3. Client must be positively identified by valid ID card, driver's license or passport and verify their name and date of birth. We recommend the Collector does not touch the ID if possible. This can be achieved by the Client placing the ID on the countertop or workspace.
4. Collector places the collection device on the desktop or workplace then steps back to allow the Client to retrieve for specimen collection.

5. Have the Client open the device packaging.
6. Have the Client grasp the handle and position the cotton pad under the Client's tongue.
7. The Client must not speak or bite the device during the collection.
8. The Collector must remain in the room with the Client until the collection is complete.
9. The collection device must stay under the tongue until the Volume Adequacy Indicator turns **BLUE**.
10. The Volume Adequacy Indicator should turn blue in 2–5 minutes.
11. If the indicator fails to turn blue, instruct the Client to discard the device, then have the client drink water, wait an additional 10 minutes and recollect with a new device.
12. The Client secures the specimen by taking the following steps:
    - Firmly hold the transportation tube upright.
    - Remove the red cap by pushing upward with the thumb.
    - Be sure the liquid does not spill.
    - Grasp the handle of the collection device and remove from mouth.
    - Place device pad first into the transport tube.
    - Replace the red cap and push down until it snaps into place.
    - If the sample is visibly discolored, specimen must be recollected.
13. Using separate pens have the Client place their initials on the tamper-evident specimen seal line [Donor Initials]. This is to acknowledge the specimen has been sealed in the Client's presence and is indeed their sample.
14. Have the Client close and seal the specimen in front of the Collector. Ensure the lid is firmly snapped or tightened and locked into place and is not crooked or loose to prevent leakage during transport to the lab.
15. Have the Client seal the specimen by placing the tamper-evident seal over the lid of the vial with the ends of the tape coming down the sides of the vial.
16. Have the Client check the number on the specimen seal to ensure it is the same number on the Chain of Custody form.
17. Using two separate ballpoint pens, the Client and the Collector now take turns signing and dating the Chain of Custody form in the areas provided. Make sure the Client's printed name and signature name are the same. Clean the pen used by the Client with soap and water between each Client use.
18. The Collector must assure that all applicable information on the Chain of Custody form is complete.

PREPARE THE SPECIMEN FOR SHIPPING TO THE LABORATORY

1. If utilizing a two-part form, the Client removes the bottom (YELLOW) copy of the Chain of Custody form and retains it for collection records. The Client now folds the top (WHITE) copy of the Chain of Custody form places it in the back pouch of the specimen transportation bag. Be sure to fold the Chain of Custody form with the information on the inside to be mindful of sensitive HIPAA information.
2. Have the client place the capped, sealed specimen vial in the front pouch of the specimen transportation bag (the pouch with the absorbent pad) and seal the bag by removing the adhesive strip and folding the flap down over the slit.
3. Have the client place the sealed bag into the provided shipping material (box, bag etc.)
4. Have the client dispose of any waste materials created during the collection process in waste receptacle.
5. Clean work surfaces with 10% bleach disinfecting solution and allow to fully dry.
6. Ask client to remove gloves and recommend that they wash hands with soap and water
7. Specimens should be shipped on the same day of the collection when possible. Keep specimens in a secured area until they are shipped.
8. Wash hands thoroughly after collection procedure is completed.

Appendix C:

COVID-19 Touchless Collection of Urine Specimens

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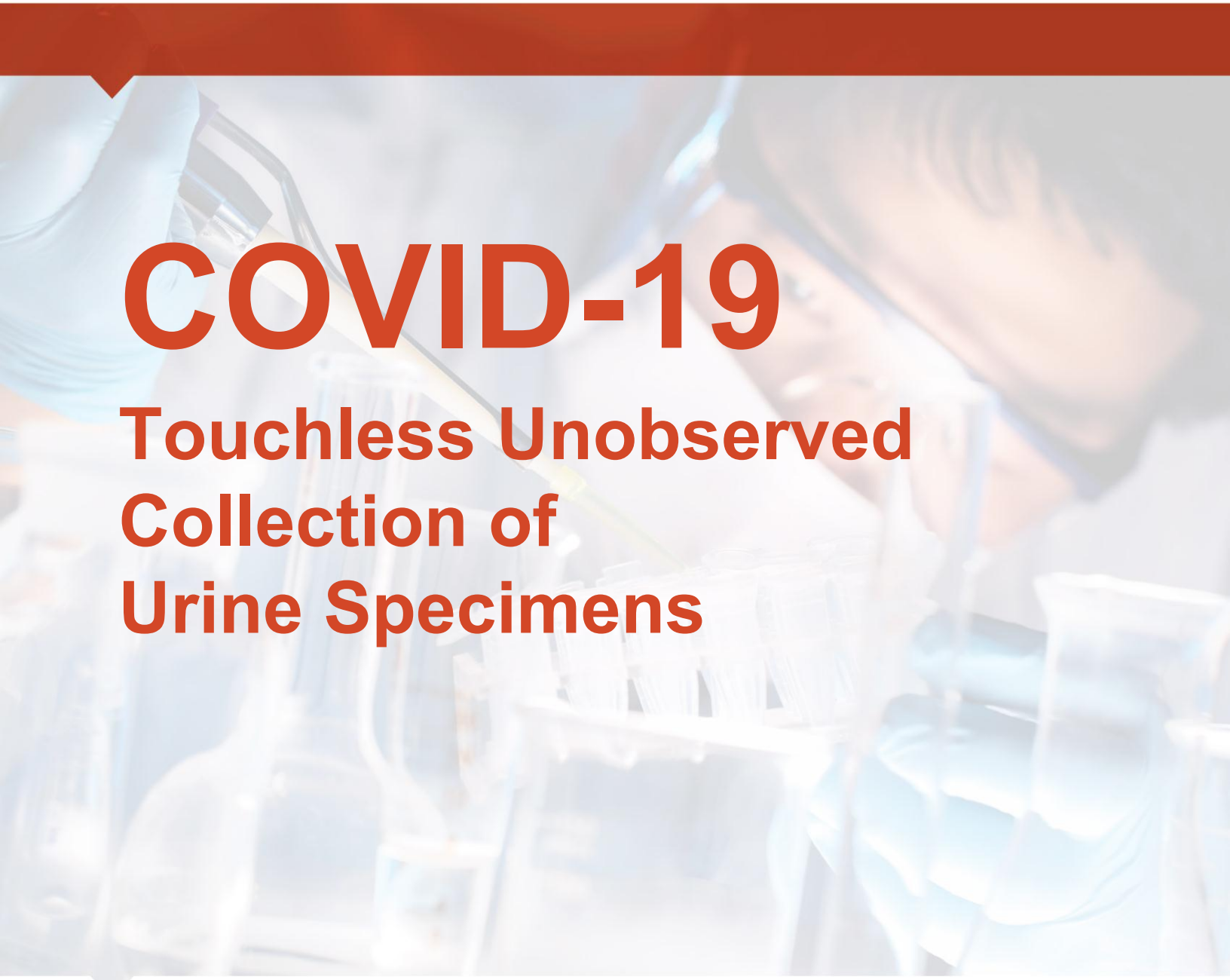

COVID-19

Touchless Unobserved Collection of Urine Specimens

Approved by Dr. Damon Borg

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COVID-19 TOUCHLESS UNOBSERVED URINE COLLECTION PROCEDURE

IMPORTANT POINT

The Collector and the Client shall keep the urine specimen in view at all times prior to it being sealed with the provided tamper-evident seal. The working space should be accessible to both client and collector while **maintaining a distance of 6 feet from the workspace**. When each person is operating in the workspace, both should **maintain a distance of 6 feet from each other** so they are not sharing the space at any one moment.

Cordant recommends ***not*** proceeding with the collection if the client is visibly sick (sneezing, coughing, etc.).

PRIOR TO COLLECTION

- Collection facilities must be clean, well-lit and dedicated solely to urine collections during the collection process.
- Water sources must not be available to the Client for specimen adulteration.
- It is recommended that all collection facilities utilize blue septic dye to deter patients from substituting the sample with toilet water.

COLLECTION

1. All work surfaces, including pens, should be sprayed and wiped down in between every collection USING 10% bleach disinfecting solution (1 part bleach to 9 parts water). Allow surface to completely dry. Collector and Client must wear gloves at all times.
2. Have client pull up sleeves to ascertain that they are not hiding anything. Have Client wash their hands thoroughly with copious amounts of water to thwart attempts to conceal items on or around the hands and arms. Have client place on gloves.
3. Client must be positively identified by valid ID card, driver's license or passport and verify their name and date of birth. We recommend the collector does not touch the ID if possible. This can be achieved by the client placing the ID on the countertop or workspace.
4. To avoid tampering, have the Client empty pockets, remove outer clothing, purse, jackets, hats, scarves, etc.
5. All personal belongings, such as a purses, bags, lunch boxes and backpacks are to remain outside the collection area. This includes keys, cell phones and any food or beverages.
6. Collector places the collection device/specimen cup on the desktop or workplace then steps back to allow the Client to retrieve cup and collect specimen.

7. The laboratory requires a minimum volume of 15 mL of urine.

UPON DONOR PROVIDING SPECIMEN

1. Only the Client will be handling the specimen. Place specimen on counter or workspace. The Collector visually checks the specimen for signs of contamination or adulteration (discoloration, precipitation, etc.) and notes any unusual observations in the Test Request space provided on the Chain of Custody form.
2. Check the temperature on the temperature strip. This should read between 90 and 100 degrees. Record the temperature on the form. If the sample does not fall within this range, there is a strong possibility the sample has been substituted with some other liquid or external source of urine.
3. If appropriate, have the client transfer the specimen from the collection device to the specimen vial.
4. Have the Client place their initials on the tamper-evident specimen seal line [Donor Initials]. This is to acknowledge the specimen has been sealed in the Client's presence and is indeed their sample.
5. Have the Client close and seal the specimen in front of the Collector. Ensure the lid is firmly snapped or tightened and locked into place and is not crooked or loose to prevent leakage during transport to the lab.
6. Have the Client seal the specimen by placing the tamper-evident seal over the lid of the vial with the ends of the tape coming down the sides of the vial.
7. Have the Client check the number on the specimen seal to ensure it is the same number on the Chain of Custody form.
8. Using two separate ballpoint pens, the Client and the Collector now take turns signing and dating the Chain of Custody form in the areas provided. Make sure the Client's printed name and signature name are in fact the same. The pen the client uses should be cleaned between each use with soap and water.
9. The Collector must assure that all applicable information on the Chain of Custody form is complete.

PREPARE THE SPECIMEN FOR SHIPPING TO THE LABORATORY

1. If utilizing a two-part form, the Client removes the bottom (YELLOW) copy of the Chain of Custody form and retains it for collection records. The client now folds the top (WHITE) copy of the Chain of Custody form places it in the back pouch of the specimen transportation bag. Be sure to fold the Chain of Custody form with the information on the inside to be mindful of sensitive HIPAA information.
2. Have the Client place the capped, sealed specimen vial in the front pouch of the specimen transportation bag (the pouch with the absorbent pad) and seal the bag by removing the adhesive strip and folding the flap down over the slit.
3. Have the client place the sealed bag into the provided shipping material (box, bag etc.)

4. Have the client dispose of any waste materials created during the collection process in the waste receptacle.
5. Clean work surface with 10% bleach disinfecting solution and allow to fully dry.
6. Have the client remove their gloves and recommends that the client wash their hands with soap and water.
7. Specimens should be shipped on the same day of the collection when possible. Keep specimens in a secured area until they are shipped.
8. Wash hands thoroughly after collection procedure is completed.

SPECIMEN REJECTION CRITERIA

A specimen may be rejected if one or more of the following occurs:

- The specimen is blue or green in color from adding water to it from the toilet bowl. Clearly state this fact on the Chain of Custody form and send the specimen to the lab.
- The specimen temperature is above or below the designated temperature range (90–100 degrees Fahrenheit). Discard the specimen and request another from the Client.
- There is a distinct smell of bleach or chemicals in the specimen. Annotate on the form and send the specimen to lab.
- There is an insufficient volume of specimen. Discard the specimen and request another from the Client. Insufficient volume is considered to be less than 15 mL.

IN THE EVENT A SPECIMEN HAS BEEN REJECTED

1. Inform the Client that the specimen does not meet the required standards for acceptance, and they will need to provide another specimen. The Client should not consume more than 8 oz. of fluid within an hour prior to a specimen being collected in order to avoid a dilute specimen.
2. If the Client fails to comply with the Collectors requests, take the following actions:
    a. Notify the requestor of the issue.
    b. Denote the specifics of the collection event on the Chain of Custody form and retain for any necessary documentation.

ADDITIONAL NOTES

- Specimens left at room temperature longer than 7 days may produce unreliable results for some drugs and metabolites.
- Minimize the number of people handling specimens.
- Specimens received in the laboratory unlabeled cannot be tested without approval.

- Specimens with lids that are not properly closed may leak out during shipping and may not contain sufficient quantity for testing.
- The consumption of more than 8 ounces of fluid prior to a collection could produce a dilute specimen.
- Collector must process only one specimen at a time.

Appendix D:

Example Audit Checklist

Cordant Health Solutions

Collection Audit Checklist

Designated Inspector: _____

Collection Site: _____

Objective: Adequate facilities		
	Yes/No	Comment
1) Does the facility meet the specifications necessary for both monitored and observed collections?		
2) Is handwashing available for client/collector in collection station?		
3) Is the collection area clean and free of debris?		

Objective: Adequate fire prevention, occupational safety and health laws are known, posted and observed.		
	Yes/No	Comment
1) Is there a written protocol available defining the steps to be followed in the event of an emergency?		
2) Are the protocols for physical distancing being observed?		
3) Is there a fire extinguisher present?		
4) Are there adequate fire prevention, occupational safety and health laws known, posted and observed?		
5) Are there fire and safety manuals?		
6) Are there exit signs clearly posted?		
7) Is there food in the specimen refrigerator?		
8) Is there ample workspace? Well lit and arranged to minimize problems in transportation and communication?		

Objective: Proper training and observance of safety and procedures.		
	Yes/No	Comment
1) Is there a collection protocol on site?		
2) Is there signage with proper personal protective equipment to be worn during collections? And are collectors wearing PPE accordingly?		
3) Are collection protocols observed correctly?		
4) Are collectors acting in a empathetic, professional, stigma free way?		
5) Are there both a male and female collector present?		
6) Are the collectors signed off for trauma informed care training?		
7) Are the location hours of operation clearly posted?		
General Comments and Observations not noted above:		

Signature:_____ Date of Inspection:_____