

Lake County Health Department and Community Health Center

Focused Risk Assessment Form

Department:	Clinical Compliance	Date:	9/30/24
Title:	Focused Risk Assessment (Contract Lab)		
<p style="text-align: center;">Risk Identification</p>	<p>Hazard Recognition: Sample Collection/Handling/Labeling Error</p> <p>Risks to Patient Safety:</p> <ol style="list-style-type: none"> 1. Delay in receiving results/treatment/care which can negatively impact continuity of care. <ul style="list-style-type: none"> ▪ A delay in receiving lab results can cause a delay in diagnosis and treatment, misdiagnosis and incorrect treatment, heightened anxiety/stress for patients waiting on crucial lab results and can delay stopping the spread of infectious disease. 2. Patients might need to return for a second blood draw. This has the potential to cause pain to the patient at the draw site and bruising. This can also increase chance of infection. 3. Patients might not return for a redraw or to leave a new urine sample when they need to. Lack of lab results can lead to undiagnosed medical conditions. 4. Specimen mix up between patients could result in patients receiving the wrong test results. This could ultimately lead to patients receiving treatment based on another patient’s results. <p>Risks to Clinical Ops:</p> <ol style="list-style-type: none"> 1. Rescheduling patients takes an appointment slot that another patient could have been scheduled in. 2. Time spent entering incident reports and answering phones related to delayed lab results. <p>Information Collection/Stakeholder Input:</p> <ol style="list-style-type: none"> 1. Health Care Safety Zone incidents reviewed 2. On site observation of lab staff/lab process 3. Annual staff competency 4. LabCorp specimen collection policy reviewed 5. Monthly audits conducted by Clinical Support Analyst/Practice Managers 		
	<p style="text-align: center;">Risk Analysis</p>	<p>Risk Frequency:</p> <ol style="list-style-type: none"> 1. 19 Incidents related to sample collection/handling/labeling errors were reported in Health Care Safety Zone in Q3 (July-Sept 2024). <p>Root Cause Analysis:</p> <p>Causes Include:</p> <ol style="list-style-type: none"> 1. Phlebotomist error 	

- Improper collection (wrong tube/container)
 - Improper handling (not inverting tubes properly, not spinning when needed)
 - Improper storage (leaving specimen room temperature when needing to be refrigerated)
 - Incorrect patient ID
2. Lack of/gaps in education and training regarding collection/handling/labeling procedures
 - Gaps in training related to state lab processing and looking for recurring orders (such as HIV viral load)
 3. Lack of communication between LCHD staff and phlebotomists
 - Provider not entering order/wrong order
 - Phlebotomists and LCHD staff not always communicating when there are mix ups with specimen
 4. Language barriers
 - Phlebotomists have a harder time verifying patients when they do not speak the patient's primary language.

Vulnerability Assessment: Identify areas where the healthcare facility is most vulnerable.

1. Malpractice lawsuits for diagnostic errors
2. Decreased patient satisfaction could lead to the patient not returning to the County
3. Damage to the County's reputation

Risk Evaluation

Prioritization: Rank risks based on their severity and likelihood.

1. These incidents are ranked **Medium**
 - **Likelihood:** 5 – Very Likely/More Than One Documented Incident
 - **Severity:** 2 – Minor, Short-term Injury/First Aid Tx Required/Minor Financial Loss.

SEVERITY	LIKELIHOOD				
	1 = Very Unlikely	2 = Unlikely	3 = Possible National Trend in Healthcare	4 = Likely One Documented Incident	5 = Very Likely More than one Documented Incident
5--Catastrophic (Unexpected death, catastrophic financial loss)	Low	Medium	High	High	High
4--Major (Permanent injury, medical treatment required, moderate financial loss)	Low	Medium	High	High	High
3--Moderate (Semi permanent injury, medical treatment required, moderate financial loss)	Low	Low	Medium	High	High
2--Minor (short-term injury, first aid treatment required, minor financial loss)	Low	Low	Low	Medium	Medium
1--Negligible (No injury, no treatment required, no financial loss.)	Low	Low	Low	Low	Low

		Assigned To:	Get Well Date:
<p>Intervention Strategies/ Action Planning</p>	<p>Current Interventions: Implemented Strategies to Mitigate Risk:</p> <p>1. Each lab incident is followed up on by the Clinical Support Analyst and LabCorp managers who investigate incidents and reeducate staff on policies and procedures.</p>	Clinical Support Analyst/ LabCorp Management	Ongoing
	<p>2. Specimen log created to document specimen hand-off. Implemented at BMB and Zion, will expand based on number of hand-off errors at other locations.</p>	Phlebotomist/ MA	Completed/ Ongoing
	<p>3. Improved communication by creating Teams channel for site staff and phlebotomists to discuss specimen/order issues.</p>	Care Teams/ Phlebotomist	Completed/ Ongoing
	<p>4. Monthly site meetings between Practice Managers and LabCorp Leadership.</p>	LabCorp Management/ LCHD Staff	Completed/ Ongoing
	<p>5. Monthly leadership meetings and monthly incident review with Clinical Support Analyst and LabCorp.</p>	Clinical Support Analyst/ LabCorp Management	Completed/ Ongoing
	<p>6. Dual language sheet for verifying patient ID and explaining draw process created.</p>	Phlebotomists	Completed/ Ongoing
	<p>Risk Mitigation and Control Preventive Measures:</p> <p>1. Ensure all phlebotomists are trained/educated on proper collection, handling and labeling of lab specimen.</p>	LabCorp Management	LabCorp Training Process

<p>2. Phlebotomists should always use two patient identifiers and have patients watch the correct patient label go on their specimen to avoid labeling errors.</p>	<p>Phlebotomist</p>	<p>Ongoing</p>
<p>3. Phlebotomists should use Accudraw in LabCorp Link to ensure they are using the correct tubes, collecting the number of tubes needed and drawing the tubes in the correct order.</p>	<p>Phlebotomist</p>	<p>Ongoing</p>
<p>Safety Protocols:</p> <p>1. LCHD Policies and Procedures are reviewed and updated at least every 3 years.</p>	<p>Physical Health Admin</p>	<p>Ongoing</p>
<p>2. LabCorp Policies and Procedures</p> <ul style="list-style-type: none"> ▪ LabCorp Code of Conduct and Ethics ▪ Corporate Compliance ▪ LabCorp Supplier Code of Conduct 	<p>LabCorp Management</p>	<p>Ongoing</p>
<p>Training and Education:</p> <p>1. Phlebotomists receive onboarding with LCHD which includes Nextgen training. Nextgen training shows how to check provider orders to ensure all lab specimen are collected.</p>	<p>Clinical Education and Training Team</p>	<p>Ongoing</p>
<p>2. Phlebotomists are required to have a phlebotomy certification, have completed a training program from an accredited agency, or have 1-2 years' experience minimum as a phlebotomist.</p>	<p>Phlebotomist</p>	<p>Phlebotomist</p>
<p>3. Phlebotomists complete e-learning through Relias and LabCorp regularly. Day 2 of onboarding increased to allow for initial Relias completion.</p>	<p>Phlebotomist</p>	<p>Ongoing & TBA (Next Phlebotomist Onboarded)</p>

	<p>Monitoring and Review</p> <p>Ongoing Monitoring:</p> <ol style="list-style-type: none"> 1. HCSZ lab incidents monitored on a regular basis and reviewed with LabCorp management. <hr/> <p>Review and Update: Periodically review and update the risk assessment based on new data or incidents.</p> <p>Feedback Loop: Incorporate feedback from ongoing monitoring to continuously improve risk management.</p> <ol style="list-style-type: none"> 1. Periodically review interventions strategies that have been implemented to decrease lab errors. <p>Documentation and Reporting</p> <p>Clear Records: Keep detailed documentation of all risk assessment activities.</p> <ol style="list-style-type: none"> 1. Follow up on risk assessment activities every 6mo-1 year. <p>Reporting: Establish a process for reporting findings to relevant stakeholders (ex. Governing Board) and regulatory bodies (ex FTCA).</p> <ol style="list-style-type: none"> 1. Q3 2024 Sample Collection/Handling/Labeling Error Risk Assessment will be presented to the Executive Team in October 2024 and to Governing Council in November 2024. 2. Quarterly risk assessments shared annually during the HRSA FTCA deeming process. CRPS Management report presented to the governing council annually. 	<p>Clinical Support Analyst, Clinical Compliance Manager, Practice Managers, Nurse Managers, and LabCorp Management</p>	
Date Completed:	10/10/2024		
Completed By:	Caitlin Brehm, Clinical Support Analyst & Angie Smith, Clinical Compliance Manager		