**RFP 24-78221**

**TECHNICAL PROPOSAL**

**ATTACHMENT F -Revised**

**Instructions: Please supply all requested information in the areas shaded yellow and indicate any attachments that have been included to support your responses.**

**SECTION 1: MANDATORY REQUIREMENTS  
  
Please provide a response of “yes” or “no” to indicate if the mandatory requirement shall be met by the respondent and its proposed solution. Respondents are advised that selecting “no” for any of the mandatory requirements may be grounds for disqualification from further consideration.  
  
Minimum Requirement 1**: The respondent has successfully implemented a similar solution for at least one state health department in the previous 5 years. If YES, please specify the state health department(s) below.

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| Yes, Axis is currently working with the Indiana State Department of Health. During the contract period, Axis worked with the State to develop (within months) interfaces with the Indiana Coroner Case Management System and Management Performance Hubs that include all data since the start of the contract, has effectively administered the State level contract while continuing to serve the County coroners without invoicing or billing errors, has increased the scope of the DOH Comprehensive Panel by 10% (30 new analytes!), incorporating important changes in the toxicology landscape during the contract term enabling the State to effectively monitor local trends and report to the CDC. During the contract period, Axis expanded County utilization of the program to the greatest percentage since the enactment of the State law [IC 36-2-14-6(a)(b)(4)]. Axis regularly provides a utilization report to the IDOH which reports and trends Indiana County submissions at the specimen level.  Axis also currently serves the Commonwealth of Kentucky Medical Examiner System and has developed a strong partnership that includes the public health information tracking desired by the Commonwealth. Axis provides forensic toxicology testing of blood, urine, and vitreous to all Kentucky Counties and Regional Medical Examiner offices. Axis works with the state office to manage the testing provided consistent with their statewide mandate. In addition, Axis assists with training, testimony, grant proposals, and reporting to Kentucky’s Violent Death Reporting System and the statisticians at the University of Kentucky who are consolidating and working with the toxicology data to identify ways to help the citizens of Kentucky.  Axis has served various districts in the State of Florida for many years. When the State developed a grant-funded program to pay for testing, Axis worked with the districts and the State to develop a billing process that enabled the districts to utilize the state funds.  Axis has worked with the Nebraska Department of Health in conjunction with the State’s largest pathology group to implement testing, reporting and invoicing to the State’s Opioid to Action grant for Nebraska county State’s Attorneys (the investigative equivalent to a county coroner). |

**Minimum Requirement 2**: The respondent must have available a web-based electronic platform, that IDOH will be granted access to for accessing all results and samples submitted.

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| Yes, Axis maintains a standard web-based Case Management Portal, to which all stakeholders (coroners, pathologists and IDOH) have access. There are various benefits to the Case Management System, including the ability to provide access to all stakeholders, the ability for coroners to track the receipt of their cases and whether anything is needed to bring them to completion, and the ability to download PDFs of testing reports individually or in a batch. The system also notifies stakeholders of unviewed cases unless the individual portal user has opted out of notifications.  In addition, as required by the prior RFP, Axis developed and maintains two interfaces required by the State. One is to Indiana’s Coroner Case Management System and the other to Indiana’s Management Performance Hub. Axis met the specifications provided by the State for these two interfaces and worked with its LIMS vendor and the vendors responsible for building these systems for the State to ensure that the testing results flow to Indiana’s other systems. |

* + 1. **General Requirements and Definitions**
       1. Please list any additional terms and definitions used by your company or industry that you would like the State to consider incorporating in the contract. The State will not accept terms and definitions introduced after award during contract finalization and implementation.

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| Axis has reviewed the requirements. The State’s terms and definitions used in the RFP align with Axis’ standards. Axis does not have any additional terms or definitions to provide. |

* + - 1. Please confirm you have carefully reviewed all requirements listed in RFP Section 1.4. Should your company have any exceptions, substitutions, or conditions for the State’s consideration, please list them below. The State will not accept exceptions, substitutions, or conditions introduced after award, during contract finalization and implementation.

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| Axis has reviewed the requirements and does not have any exceptions, substitutions, or conditions to propose because we are able to fulfill all the RFP requirements as stated. |

* + - 1. On attachment K indicate the respondents’ ability to test for all listed drugs per each testing methodology.

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| Axis has reviewed attachment K and is prepared to deliver the requested IDOH Comprehensive Panel. Per attachment K, Axis can or will be able to test for all requested drugs. |

* + - 1. When the drug and test methodology result in “No, but within six months” explains the respondents’ assurance to meet the six-month ability. In the event six months is not achievable, explain how the respondent will fulfill the State’s requirement.

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| Axis has extensive experience utilizing rapid method validation, bringing a newly discussed drug to client availability in as fast as 1 month. Typical validation timeline to add rapidly validated drugs is within 3 months from acquisition of reference standards. Axis utilizes this process extensively to incorporate emerging compounds and NPS compounds into our testing library, but has also utilized this process on drugs that would not be considered emerging or NPS. Furthermore Axis sees no reason to believe the drugs on attachment K that resulted in “No, but within six months” would not be able to complete validation within the required timeframe.  Per the question though, in the event six months is not achievable, per the Q&A response regarding this question, Axis would be willing to discuss “(d)uring the life of the contract, IDOH and the contractor (would) discuss to mutually reach a resolution on a case by case basis.” |

* + - 1. When a drug and test methodology result in “no” explain why.

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| Axis did not respond “No” for any drug. |

Required questions that must be answered.

1. Please describe your organizational capacity and infrastructure including laboratory services.

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| As the incumbent laboratory, Axis already has the established testing capacity to perform the testing described. Axis Forensic Toxicology receives cases daily from more than 700 clients throughout The United States. We operate near 70% of our overall capacity (which includes current casework from Indiana coroners) and continue to maintain more than enough capacity to continue completing work for the State in a timely manner. Typical turnaround time for cases is within 10 business days of receiving the case in-house. Axis is currently returning results to the State in 8.44 business days. Axis has met or exceeded the turnaround time expectations of the current contract and is prepared to meet the State’s turnaround expectations for the proposed contract.  Axis provides forensic toxicology testing and litigation services to medical examiners, coroners, reference laboratories, state crime laboratories, federal, state, and local law-enforcement agencies, government agencies, sexual assault centers, attorneys, courts of law and correctional centers. The nature of death investigation in the United States means that Axis’ clients range in size from a single county to an entire state’s department of health or medical examiner system. Axis currently maintains several statewide contracts and many multi-jurisdictional contracts as well. At the request of OR with the permission of its clients, Axis contributes to various state public health data collection activities, helping our clients address the drug trends within their communities as well as closing out individual cases. We serve many other NAME-accredited offices throughout the United States.  Axis engages with clients routinely through multiple avenues, from in-depth state level toxicology discussion panels to individual client discussions about drug trends in a single area within the United States. With more than 700 clients throughout the United States, each of Axis’ clients has the benefit of utilizing national drug trends to update on-going testing. When a new drug is suspected in a certain area of the country, that drug is added to Axis’ client offering through rapid method validation, and that drug is added to panel offerings for all clients. Axis’ clients do not have to rely only on local toxicology involvement alone, but gain the benefit of a national partner to continue to stay on the cutting edge of toxicology testing. Axis understands that static panels do not serve the best interest of it’s clients and for that reason Axis continuously updates it’s panels when new drugs are identified, rather than updating on a set schedule. Axis understands that providing testing to clients quickly often is the difference on a final toxicology report.  Axis would continue to provide a testing panel that is in alignment with the scope of testing outlined in attachment K of this RFP. While some of the individual drugs tested in the IDOH Comprehensive Panel may differ from our standard core panels, the process of testing those drugs, and the validity of the results would be of an equal scientific and quality standard as those offered through our standard core panels.  Axis has created a multi-pronged approach to broadly screening and confirming all samples from Indiana coroner’s and pathologists utilizing analytical methods and instrumentation with the greatest sensitivity and best capability of identification. Axis completes all screening through High Performance Liquid Chromatography Quadrupole Time of Flight Mass Spectrometry (LC-QTOF/MS) and Headspace Gas Chromatography (GC-FID) technology. Once these initial screening results are completed, confirmation testing is performed utilizing Gas Chromatography Mass Spectrometry (GC-MS), High Performance Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS), High Performance Liquid Chromatography Quadrupole Time of Flight Mass Spectrometry (LC-QTOF/MS) and Headspace Gas Chromatography (GC-FID). The drug specific screening of all samples (rather than drug class screening as is the case with ELISA technology) ensures that IDOH and Indiana coroners/pathologists would receive the most accurate screening and identification of all drugs in the IDOH Comprehensive Panel.  Axis provides a comprehensive and systematic approach to the analysis of biological fluids, tissues and drug dosage forms on behalf of our clients throughout the United States. As part of the forensic program, Axis follows strict chain-of-custody and confidentiality guidelines as well as providing complete professional consultation and expert witness testimony. Our chain of custody starts with prepaid Priority Overnight shipping through our preferred carrier FedEx. These prepaid shipping labels (as well as collection supplies including boxes, tubes, bottles, needles, syringes, and packaging material for transport) are provided to coroners and pathologist at no cost. A supply is sent to each user of toxicology services either by request or on a scheduled cycle to ensure submitting officials are never without supplies. In the event of an emergency (either through a submitting official running out, or a shipment taking longer than anticipated) Axis is committed to providing client supplies overnight or through whatever means to ensure continuity for Indiana coroners and pathologists.  The toxicology test services offered by Axis were developed through our team of experts and consultation with recognized authorities within the forensic toxicology community. As a result of our on-going research efforts, new analytes are constantly validated and introduced into laboratory services. Additionally, Axis recognizes that emerging compounds drive much of what the future of toxicology testing will provide to our clients and partners. Due to this fact, Axis spends the vast majority of its R&D time and resources on emerging compound monitoring and method development. This has led to 30 individual drugs being added since the beginning of the current IDOH contract in 2019. The fundamental goal of Axis’ panel development is to implement new drugs quickly with validated methodology, and THEN evaluate whether or not the drug warrants continued testing. Axis finds more value in quickly bringing drugs to our core panels for clients, rather than maintaining separate surveillance that is not readily available to our client base.  Axis’s company structure ensures business stakeholders, laboratory expert input, and client input is used to drive business and product development decisions. This structure allows for a strong foundation that incorporates science-based information and business practices that are mutually beneficial to the business, its employees, and the clients we serve. This structure ensures Axis remains a good steward to the resources and services it provides to the community and our clients and meets the values the company stands on:  Innovation | Relevance | Integrity | Leadership  Axis’ toxicologists routinely provide consultation regarding the returned results and have provided testimony for trials throughout the United States. Axis’ operations management team consults with the coroners and medical examiners to ensure that critical and complex cases receive special handling as needed to ensure that Axis is providing timely, relevant and accurate testing results. This consultation can take many forms, from proactive communication from a submitting official prior to shipment all the way through a proactive communication from Axis when something is seen in the analytical testing data that may be unexpected in conjunction with the history of the submitted case. In these instances, Axis works individually with submitting officials to make sure that testing is completed quickly and exceeds the expectation of what the submitting official expects. In instances of limited collection volume, Axis coordinates with the submitting official to ensure that testing is completed in a way that is most beneficial to the history of the submitted case.  KEY LABORATORY PERSONNEL  • Mattew Zollman, MBA, Director of Operations & Product Management  • George Behonick, Ph.D., F-ABFT - Laboratory Director and Chief Toxicologist  • Kevin G. Shanks, MS, D-ABFT-FT - Senior Toxicologist  • Stuart Kurtz, MS, D-ABFT-FT - Toxicologist  • Katherine Alexander, BS, MBA – Operations Manager  • Marcie Larson, BS – Technical Manager  Axis’s laboratory technicians are responsible for the proper receipt, handling and preparation of specimens for analysis. Laboratory personnel assigned to the testing and analyzing of laboratory results (i.e. Analytical Chemist I, II, and R&D Scientist) at Axis Forensic Toxicology meet or exceed the minimum laboratory experience and education requirements as set forth by the American Board of Forensic Toxicology, CLIA, and CAP for high complexity tests. Consistent with regulatory requirements, cases are reviewed post-analysis by an ABFT-accredited toxicologist described above.  All laboratory employees are required to complete annual continuing education which includes but is not limited to scientific conferences, presentations, scientific articles, or training offered by our Toxicology Team. Laboratory personnel are trained and supervised by the laboratory managers listed above with oversight by our Laboratory Director. All laboratory employees are also required to complete multiple competency programs throughout the year to ensure continued adherence to established standard operating procedures in all areas. These competency assessments (as well as all initial and annual training) are logged and recorded as part of each employee's training record. All work is performed at Axis’ laboratory in Indianapolis. Axis employs 40+ Hoosiers and Indiana college graduates in STEM careers, contributing to the Indiana life sciences industry. More than 50% of Axis’ employees are female. BioCrossroads named Axis as a Top 100 Life Science employer in Indiana.  Supporting Axis’ scientific team is a group of experienced and committed administrative employees. Axis is committed to providing a knowledgeable and efficient client services model that ensures the most qualified individuals meet the needs of our clients. Depending on the State’s need, each area of Axis may be reached by calling 317-759-4TOX or via the email/website form. |

1. What is your organization’s experience and service history in providing toxicology testing of blood, urine, and vitreous samples?

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| Axis (formerly the forensic toxicology division of AIT Laboratories) has been testing blood, urine, and vitreous for forensic purposes for over 30 years. Axis is dedicated to forensic toxicology and its mission is to help bring closure to families and communities by providing timely and accurate toxicology results, accompanied by a commitment to client service.  Axis is the only national laboratory whose standard offering includes a “whole case” approach testing blood, urine and vitreous. Because Axis’ standard Comprehensive Panel with Analyte Assurance ™ and Drugs of Abuse Panel include the whole case approach, Axis has deeper experience testing urine and vitreous specimens than other forensic toxicology laboratories. Utilizing our whole case approach means that if blood, urine and vitreous are submitted, Axis will test for all three specimens without charging the client additionally to run the urine or vitreous specimens. For this reason (and that the cost to the client is no different if they submit urine and vitreous) Axis has a deeper understanding testing urine and vitreous samples. As blood specimens are the gold standard in forensic toxicology, Axis has an even deeper understanding of blood testing, backed by accreditations from the College of American Pathologists, American Board of Forensic Toxicology, ISO/IEC 17025:2017 international standard for forensic testing and calibration laboratories, and Clinical Laboratory Improvement Amendments.  Axis is dedicated to forensic toxicology exclusively and its experience is 100% relevant to the State’s toxicology needs. |

1. What is your organization’s experience working with local entities to provide toxicology testing?  Please provide at least 2 examples.

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| Axis excels at working with all levels of government entities to ensure testing is completed, reporting is accurate and timely to all stakeholders, and invoices are accurately and timely sent to the correct agency depending on each individual government contract.  Axis works with hundreds of individual local entities to provide toxicology testing. Axis works with all counties within the Commonwealth of Kentucky and 97% of the counties in Indiana. Axis serves the majority of counties in several states including Nebraska, South Dakota, Kansas, and Wyoming, as well as hundreds of other counties across the United States and its territories.  Specifically, Axis has worked closely with the Marion County, Indiana, Coroner’s Office. They participated in our Postdoctoral Fellowship program. We are their exclusive laboratory for non-overdose testing done outside of the current ISDH contract. We have assisted them and the Marion County Board of Health in the development of grant proposals. We have also worked closely with the Lake County, Indiana, Coroner’s Office. As an example, Lake County needs a specific report regarding their xylazine cases that Axis provides to their specifications upon request. Many more examples are available upon request.  Axis provides county level utilization reporting to the State of Indiana above and beyond what is required for test result reporting and invoicing. Additionally, Axis works with each County to provide any requested reports.  Axis’ systems are innately flexible to handle the requirement to balance county and state needs for reporting, supplies, invoicing, etc. The Commonwealth of Kentucky, for example, (similar to Indiana) maintains a central State contract which is allows for reporting and billing to the State while also allowing reporting and supply shipment to individual counties. Within the State of Indiana, Axis manages County level supply requests, account updates, reporting, inquiries, and all other needs by working directly with County level officials that have been designated typically by the County Coroner or other authorized individual. Axis recognizes that while the contract for services is through IDOH, the individual County Coroner or pathologist is the primary daily point of contact for submission and other testing needs. To that end, Axis proactively engages all local partners (County coroners and forensic pathologists) as the primary stakeholder at the case level, even when they are a part of a larger, overarching contract with the same level of service that the contract holder receives.  In some other local entities outside Indiana, coroners/pathologists and medical examiners prefer to keep their cases separate in the Axis Case Management Portal, which is easily accomplished because Axis can create an individual account for each pathologist to view his/her cases regardless of the County. Each County can review all of their cases regardless of pathologist that submitted the case. Billing in those situations can be aggregated across the office or maintained separately. To our knowledge, Axis is the only laboratory whose account structure allows this type of flexibility and convenience for Counties, pathologists, and the State. |

1. What is your organization’s experience working with state government to provide a specific service?  Please provide at least 2 examples.

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| Axis is currently working with the Indiana State Department of Health. During the contract period, Axis worked with the State to develop (within months) interfaces with the Indiana Coroner Case Management System and Management Performance Hubs that include all data since the start of the contract, has effectively administered the State level contract while continuing to serve the County coroners without invoicing or billing errors, has increased the scope of the DOH Comprehensive Panel by 10% (30 new analytes!), incorporating important changes in the toxicology landscape during the contract term enabling the State to effectively monitor local trends and report to the CDC. During the contract period, Axis expanded County utilization of the program to the greatest percentage since the enactment of the State law [IC 36-2-14-6(a)(b)(4)]. Axis regularly provides a utilization report to the IDOH which reports and trends Indiana County submissions at the specimen level.  Axis has served the Indiana State Department of Health since 2020. Axis provided the State with a comprehensive onboarding process, enabling coroners to quickly and effectively begin submitting cases. During the time period that Axis has provided service to the State of Indiana, Axis has met all commitments as outlined contractually or otherwise. Additionally, many of the changes that have been beneficial for the State and County coroners were implemented upon recommendation from Axis as their expert in forensic toxicology testing. Axis has enjoyed an outstanding working relationship with the State of Indiana, as demonstrated by this list of successful collaborative initiatives, allowing Axis to serve the State well:   * Developed custom panel in response to State RFP commitments. * Regularly expanded the panel as emerging compounds were identified, and intentionally communicated the changes to the coroners, the Indiana Coroner Association, Indiana pathologists and the State Department of Health. * Developed custom requisition overprints to include the ISDH Panel and to ease submission of cases by both counties and private pathologists. * Developed customized account setup procedure to allow each County to designate their preferred pathologist(s) and automate reporting to ISDH. * Developed a State specific Client Guide and recorded live webinars for active discussion and for use during onboarding, coroner transition, new staff. * Performed outreach after county election cycles to ensure correct account setups including authorized users, supply shipping, requisition overprints, training, etc. * Developed billing process to ensure that the State was only billed for testing contracted under the RFP. All other testing billed to coroners/pathologists. * Worked with State stakeholders to develop the State’s two required custom reporting interfaces. * Regularly provide county utilization report to the State. * Generated positivity report for the State to validate ordering effectiveness. * Provided post-doctoral fellowship rotation in toxicology (part of a year-long training program for pathologists that develops their ability to apply their doctoral studies to medicolegal death investigation) for the Marion County Coroner’s office.   Axis also currently serves the Commonwealth of Kentucky Medical Examiner System and has developed a strong partnership that includes the public health information tracking desired by the Commonwealth. Axis provides forensic toxicology testing of blood, urine, and vitreous to all Kentucky Counties and Regional Medical Examiner offices. Axis works with the state office to manage the testing provided consistent with their statewide mandate. In addition, Axis assists with training, testimony, grant proposals, and reporting to Kentucky’s Violent Death Reporting System and the statisticians at the University of Kentucky who are consolidating and working with the toxicology data to identify ways to help the citizens of Kentucky.  Axis has served the Commonwealth of Kentucky for the better part of the last 15 years. As part of this service relationship, Axis has:   * Developed a custom panel in response to Commonwealth RFP commitments. * Developed preliminary cause of death reporting interface and special public health reporting interface. * Implemented customized panel upgrade procedure. * Developed custom billing process that aligns with and captures the upgrade approval process. * Conducted ongoing coroner education programs.   Axis has served various districts in the State of Florida for many years. When the State developed a grant-funded program to pay for testing, Axis worked with the districts and the State to develop a billing process that enabled the districts to utilize the state funds. Axis has been instrumental in helping the State and individual districts utilize the funds provided in the most efficient manner.  Axis has worked with the Nebraska Department of Health in conjunction with the State’s largest pathology group to implement testing, reporting and invoicing to the State’s Opioid to Action grant for Nebraska county State’s Attorneys (the investigative equivalent to a county coroner). |

1. What are your operations to provide detection, identification, analysis technique, quantification limit and quantification of drug compounds a Comprehensive Panel?

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| Axis prides itself on keeping current with industry best practices. Axis uses a variety of high-tech instrumentation and analysis methods such as gas chromatography (GC), mass spectrometry (MS), gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), liquid chromatography-mass spectrometry/mass spectrometry (LC/MS/MS), ultra-performance liquid chromatography-mass spectrometry/mass spectrometry (UPLC/MS/MS), and ultra-performance liquid chromatography-Quadrupole Time of Flight mass spectrometry/mass spectrometry (LC/QTOF/MS).  Axis utilizes quadrupole time of flight/mass spectrometry for detection and identification in all offered panels. Utilizing this analyte specific (as opposed to class specific) method allows updating of our ISDH and other panels to happen very rapidly, and without reliance on cross-reactivity of commercial kits typically used for immunoassay screening. Axis’ method of screening (utilizing exclusively LC-QTOF/MS) provides an opportunity for Axis to confirm the specific drug that was screened as positive. This allows for a more effective and reliable screening/confirmation relationship that immunoassay screening would provide for. Additionally, because all of Axis’ screening is performed via LC-QTOF/MS, Axis has the opportunity to retrospectively review specimen data if and when new drugs come to light. As part of its thorough service to the Counties in completing their death investigations, Axis has the ability (and currently utilizes that ability) with all specimens submitted by Indiana coroners to review data that was run previously to revisit a previously reported case to identify drugs were not known at the time of the original testing but have since been identified as drugs of concern. Utilizing this information we engage County coroners and pathologists for follow up on a case by case basis.  As screening tests become complete, confirmatory testing is begun utilizing the instrumentation referenced above. Confirmatory testing confirms the result of the screening test to state definitively that what we screened is in fact present. This confirmatory testing is performed on a second aliquot, sampled from the original parent container, in accordance with our accrediting bodies and best practices.  Axis has more than 50 laboratory-developed analytical methods. Each method is carefully developed through research and experimentation by our highly qualified Analytical Chemists, and then validated to ensure that detection, identification, proper analysis technique, quantification limit and quantification of drug compounds can be reliably obtained for the analytes of interest and the matrices submitted. Any time a new method is developed, or an existing method improved, a thorough production onboarding process is conducted, consisting of verification that the method is executable within the production laboratory, meets client needs, and performs on an ongoing basis, followed by training of personnel to the new or revised standard operating procedure, and a scheduled implementation date once the foregoing has been successfully completed.  Axis does not typically distinguish between the Limits of Detection (LOD) and the Limits of Quantification (LOQ) because we strive to validate quantitatively to the lowest level that we can detect, although there are exceptions where an analyte would be reported present below the LOQ. All confirmations are performed using GC/MS and LCMS/MS/MS instrumentation for highly accurate results.  Axis is required to perform annual reviews regarding the scope of its toxicology panels, however, Axis reviews its toxicology panels continuously. Utilizing our team of experts and consulting with recognized authorities within the forensic toxicology community, new drugs are constantly validated and introduced into laboratory services. Axis is committed to reviewing and updating the scope of its toxicology panels when new compounds are presented in the marketplace, rather than a predetermined cycle throughout the year. We believe this allows for real-time information in the marketplace to drive what is tested for in our client’s panels more efficiently that updating our panels on a predetermined schedule or cycle. Additionally, Axis recognizes that emerging compounds drive much of what the future of toxicology testing will provide to our clients and partners. Due to this fact, Axis spends the vast majority of its R&D time and resources on emerging compound monitoring and method development.  Occasionally, the State may need testing for a substance that falls outside the scope of the RFP. Axis has the resources and capabilities to meet the needs of the State in these circumstances. Axis’ chemists and toxicologists have honed their expertise over many years of non-routine testing and Axis’s instrumentation gives it access to a vast library of compounds. Axis is proud of the work it has done to help its clients with unusual or unexpected cases and materials.  Once all testing is complete, each case is reviewed individually by one of our ABFT accredited toxicologists who have the opportunity to take a holistic view of what was submitted and what is to be provided to our client in a report. Once that exhaustive review is complete, results become available to our clients nearly instantaneously through our Axis’ Case Management Portal. |

1. What is your average amount of time (days) to test a sample from the point of receipt? What is your average amount of time (days) to share analysis results with IDOH and County Coroners?

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| Axis’ approach to processing allows quick turnaround to enable coroners and pathologists to provide timely answers to their communities. Axis provides overnight shipping labels (at no additional charge) so that accessioning can begin the next business day. Once received, aliquots are immediately prepared for screening and directed testing. There is no delay between receipt and testing commencing. The certified presumptive positive results from the screen trigger an aliquot for one or more confirmatory methods, while the certified directed and negative screens are held pending forensic review of the case as whole. As soon as all results are complete, certified and reviewed, the results are released to all report recipients via your reporting methods of choice. This means that negative results can be resulted in as little as 2 business days. Axis’ recent turn-around time for reporting to the State is an average of 8.44 business days.  In circumstances where submission information is missing or unclear, Axis will issue an Affidavit requesting clarification. If the clarification needed includes the testing desired, testing will not commence until the clarification is received. Clarification of a demographic nature will allow testing to proceed while awaiting the requested information. In all cases, the information request is visible to stakeholders in Axis’ Case Management Portal as a supplement to the active outreach by Axis’ Lab Client Support personnel. This active outreach is performed for 5 business days. For Affidavits that prevent testing from commencing, after those 5 business days testing is cancelled and the submitting agency receives a report indicating that testing was cancelled. The case is then stored for 1 year as all cases are once testing is complete. During that timeframe, the submitting agency has an opportunity to reach out to us to schedule testing and correct whatever information was missing originally. |

1. ~~How do you currently share/communicate analysis results with~~ ~~IDOH and County Coroners?~~ Explain how analysis results will be shared/communicated to IDOH and County Coroners? ~~Who in your organization oversees this communication?~~

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| All results are conveyed via a report posted to the Axis Case Management Portal, which allows simultaneous release to coroners, pathologists, and IDOH staff. An email notification is sent to portal users when unviewed cases are available (users can also opt out of the email if they choose). Reports can be downloaded from the portal in a PDF format for attachment to other systems of record. If the County requests it, the report can also be transmitted via automated fax.  The State of Indiana also receives results through State-specific file transfers set up during the implementation of the current contract. These interfaces connect with the Indiana Coroner Case Management System, which the coroners may use to access and manage results, and the Management Performance Hub, which we understand to be a statewide data repository used by the State’s epidemiologist to derive actionable information from the data. As each case is completed, files are created to Indiana’s specifications and sent via secure file transfer to the State’s servers for processing into their databases.  Preliminary results may be obtained from our Lab Client Support group, and consultation regarding the results is available with our Lab Director and our other toxicologists. |

1. What is the format of the reports that your company provides to your customers?  Please provide a list of your company’s standard reports, including examples, as an attachment to your RFP response.  Please note which are available online and how the reports are delivered to your customers.

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| Axis has developed a secure Case Management Portal for reporting of all toxicology final reports to each participating coroner in the state. These results are received directly from Axis through a secure portal immediately upon completion of a final report. Our Case Management Portal allows for coroners, pathologists, and the State to all receive the same report directly from Axis by utilizing unique logins for each user. This means that County Coroners can view all cases submitted through their County (both cases as a result of the IDOH contract and those that are not), pathologists can view all cases that they are a part of regardless of the submitting County, and the State can view all reports. This happens seamlessly for the user with Axis taking care of all logistics as part of the account setup on the front end.  There is one standard report format, which is a PDF, attached. Axis reports meet or exceed the standards and requirements set forth by CAP, CLIA, ABFT and ISO/IEC 17025:2017. Toxicology reports from Axis contain all information necessary to identify the cases and its source.  Information includes\*:   * Agency name and address of client * Name of subject * Case number/autopsy number * Date of death/autopsy * Date specimens received and date of report * Identification of all case specimens * Identification of testing performed (test code and test name) * Quantitative/Qualitative test results for all case specimens * Reference ranges (therapeutic), if available, for all test results * Signature of certifying toxicologist   \*Some information must be provided by client to be included on final report  All reports are delivered via Axis’ Case Management Portal, which has many benefits including acknowledgment of case receipt and flagging of exceptions that require client response to finish testing. (Primarily a benefit to the submitting county/pathologist.) It is also possible to set up automated faxing of the same report, but the Portal provides greater functionality.  As described below, Axis maintains two results delivery interfaces with the State: the Indiana Coroner Case Management System and the Management Performance Hub. These are files in a format requested by the State and transmitted via File Transfer Protocol. Due to the format, they cannot be “attached” but they are specific to the State’s specifications.  Within months of the contract execution and within the agreed timeframe under the contract, Axis developed and implemented a critical data integration with the Indiana State Department of Health for toxicology data exchange through automated exchange into the Indiana Management Performance Hub (INMPH). Upon completion, Axis retroactively reported all cases back to the start of submissions under the contract. This Data exchange is done to the State’s specification and regularly transmitted through secure and encrypted means that required developmental time from Axis. Axis made a significant investment of programming time, validation, maintenance in order to serve the State well. This integration will continue with the Indiana Department of Health at no additional charge.  Also within months of the contract execution and within the agreed timeframe under the contract, Axis developed and implemented a reporting systems to fully integrate with the Indiana Department of Health Coroner Case Management System (INCCMS) for use with the project as it is adopted by coroners within the state.  See sample report in attached documents. |

1. ~~Do you provide technical assistance and education to IDOH and County Coroners?~~ What technical assistance and education can you provide to IDOH and County Coroners? Is there an associated cost? If so, please provide at least 2 examples.

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| Axis provides technical assistance and education to IDOH and County Coroners and pathologists. Axis routinely provides training at onboarding and upon request. Types of training available from Axis includes:   * Axis provides direct access to its experts in functional areas. For example, clients can directly contact the Laboratory team for questions regarding ordering or case status without going through a central gatekeeper. * Similarly, toxicologists are directly available by telephone or email to answer case-specific or general questions. Both Coroners and pathologists can utilize their deep expertise for assistance with the death investigation. * Webinars are conducted by toxicologists and operational leaders on various topics of interest, including how to submit cases for testing, view results, obtain supplies, etc. * On-site training at an individual County office for users, relevant to the individual needs of the County * In person training and material for the Indiana Coroners Conference on topics such as emerging drug trends, compliance with the State’s drug testing requirements, and best practices for interaction with County prosecutors. * Axis offers one of the only toxicology rotations (and the only one in the State of Indiana) for postdoctoral fellows, a week-long intensive on toxicology for qualifying staff members within the coroner system. * Blog posts, published at least monthly, including primers on specific classes of drugs, emerging drug trends and the action of those drugs upon the body, recapping presentations Axis experts have made at conferences and other trainings, announcements of upcoming product improvements. * Emails regarding Indiana specific trends and product improvements. * Visits to our laboratory: clients have been and are always welcome to come to our Indianapolis-based laboratory at any time.   Axis does not typically charge for training as we view it as part of our mission to support an effective death investigation system. |

1. Does your company have a program in place for keeping up with new emerging drugs? Please explain.

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| Axis utilizes a Working Group for keeping up with new emerging drugs. This Working Group is responsible for tracking changes in the emerging drug market, identifying compounds of interest and developing strategies for implementing them into testing. Axis uses a variety of input information to inform this Working Group including scientific literature, internally generated data from on-going casework, DEA reporting, various on-going meetings through the country for NPS tracking groups, client feedback, and a variety of online material discussing or reporting on various NPS. This group’s mindset is to proactively listen and learn what is next in terms of the NPS that need to be included in testing, anticipating our client’s needs. As Axis has a national presence in forensic toxicology and emerging drug toxicology, monitoring what is going on in the NPS landscape nationwide remains of paramount importance to ensure we are leading the nation in bringing new emerging drugs to testing in the forensic toxicology market.  While it was once acceptable to only review the emerging drug landscape on a yearly or twice yearly frequency, the pace of change and the prevalence of emerging drugs in the drug landscape makes that practice obsolete and slow. Axis is continuously monitoring the NPS landscape and will update panels with new emerging drugs as quickly as possible, as frequently as monthly if the market warrants new compounds being brought into testing that frequently.  Our process evaluates the analytes included, screening limits, detection limits and quantitation limits. Background criteria derived for inclusion into panels include, but is not exclusively limited to the following:   * In house send out referral data (frequency and cost) for directed testing and analyses by extramural reference laboratories; * Input, feedback and inquiries by medical examiners, coroners and law enforcement agencies to Axis toxicologists; * Peer reviewed case reports and communications within the field of forensic toxicology; * Relevant epidemiological reports and alerts from agencies such as the U.S. Drug Enforcement Agency (DEA), National Forensic Laboratory Information System (NFLIS), European regulatory agencies, and national poison control centers; * Information derived from technical/scientific work groups and various committees pertinent to emerging drug trends and prevalence (SOFT, AAFS); * New regulatory guidance. * NPS Discovery, which is supported by the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice   Once target compounds are identified using the above process, Axis has optimized its rapid method development processes to quickly bring those new compounds into its products including the IDOH Comprehensive Panel. Typical development and validation processes can take six months or more to implement. Axis has shortened it to a matter of weeks without sacrificing quality.  Over the life of the current contract (since 2019), Axis has added 30 drugs. Emphasizing the importance of rapid method development, these drugs were detected and reported in 240 cases within the first 6 months of being added to the panel. A traditional development and validation process would NOT have captured these drugs in those cases because they would still be in development during that period.  Axis' QTOF/MS screening includes the ability to proactively, on a real-time basis, detect newly identified compounds. By making this part of standard products or processes, Axis doesn’t need to rely upon out-of-scope monitoring to communicate detection of emerging compounds. Axis does not maintain multiple libraries that are compared against submitted casework, which then prompts discussion with the submitting agency. Axis includes anything that might be in a secondary library, in its standard library to make sure that all clients are receiving the most comprehensive and up to date panel offering at all time. There is no need for us to maintain multiple libraries or provide out of scope notifications when we’ve made the decision to include all compounds we would be able to test for in our library of drugs offered to all clients. |

1. If the IDOH requests the addition of a drug compound, how will you handle adding it to the IDOH Comprehensive Panel? What additional costs are associated with the addition of drugs to the ~~ISDH~~ IDOH Comprehensive Panel?

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| When we routinely add new analytes real-time to the scope of our testing menu, we will notify IDOH and there will typically be no additional charge. As mentioned above, one of our inputs into new test development is client request. We also offer a trace/special request process for truly one-off situations. Given the unknown costs for purchase of standards for development, if Axis adds to the panel at the request of the State, we will negotiate in good faith regarding the cost to add.  Without prompting or request from the State, Axis expanded the IDOH Comprehensive Panel by 10% (30 analytes) over the course of the current contract period at no additional charge. If these analytes were added under the current they would also have been at no charge. |

1. Does your company maintain accreditation?  If yes, please list the organizations and provide documentation of accreditation.

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| Yes, Axis maintains the highest certifications and accreditations through several bodies that impose regulatory requirements including:   * College of American Pathologists, * American Board of Forensic Toxicology, * ISO/IEC 17025:2017 international standard for forensic testing and calibration laboratories, * Clinical Laboratory Improvement Amendments. * Drug Enforcement Administration   Additionally, Axis follows the standards of the Society of Forensic Toxicology.  Obtaining and maintaining the above accreditations requires regular onsite and remote surveillance and audit activities to ensure ongoing compliance to these rigorous standards. Our robust Quality Assurance and Quality Control programs are designed to meet and exceed the above standards. |

1. Provide an Implementation Plan of what your company’s specific actions will be to successfully implement the new Contract requirements (including transition steps, if applicable) so that all of Indiana’s 92 county coroners will have toxicology testing service available on day one of the Contract start date. Please include project management for delivery of trainings, procedures to insure IDOH will not pay for tests that are not part of the contract, delivery of all necessary supplies to the county coroners, how you will address any problems or questions they would have, and anything else you feel the reviewers should know.

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| As the incumbent laboratory, Axis needs a smaller scope for implementation than a new vendor would. It would not be necessary to do any account setup or supply shipment, unless there have been recent changes at a county (which, as described above, we routinely monitor and proactively seek to update throughout the year). It would also not be necessary to set up any new reporting interfaces or billing procedures. Axis already has the relevant systems and procedures in place as described in the RFP.  Axis would recommend an announcement of the continuation of services immediately upon completion of agreement, followed by sending a refresher Client Guide, new panel scope (if necessary), and a webinar to review any other changes that would have bearing upon the coroners and pathologists. Additionally, Axis would work to make direct contact with all offices, prior to the start date of the new contract, to notify them on the continuity of service, walk through the changes to the scope of testing and any service changes to make sure that all County Coroners and pathologists are able to continue submitting cases without any disruption to utilization of the State testing program.  Should the State select a different vendor, Axis will cooperate during the transition. If county(ies) continue to submit specimens to Axis under an IDOH contract, Axis will return them to the county. |

1. What is your company’s experience with building and maintaining web based electronic platforms for the delivery of test results?

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| Axis maintains its Case Management Portal for use by all clients. It was developed to be flexible to meet the needs of all Axis clients, whether a sole proprietor office or a multi-location, multi-user office. It supports a robust Copy To function that allows Axis to report results to both the submitting entity and one or more authorized third parties.  Other important features for the benefit of the submitting county include the ability to see cases in the portal as soon as they have been accessioned and to see whether there may be questions pending regarding the submission. There are daily notifications of unviewed completed cases, as well as the ability to opt out of those notifications, if desired.  The IDOH has relied upon this capability since the inception of the current contract to access test results for all the submitting counties.  Within months of the contract execution and within the agreed timeframe under the contract, Axis developed and implemented a critical data integration with the Indiana State Department of Health for toxicology data exchange through automated exchange into the Indiana Management Performance Hub (INMPH). Upon completion, Axis retroactively reported all cases back to the start of submissions under the contract. This Data exchange is done to the State’s specification and regularly transmitted through secure and encrypted means that required developmental time from Axis. Axis made a significant investment of programming time, validation, maintenance in order to serve the State well. This integration will continue with the Indiana Department of Health at no additional charge.  Also within months of the contract execution and within the agreed timeframe under the contract, Axis developed and implemented a reporting systems to fully integrate with the Indiana Department of Health Coroner Case Management System (INCCMS) for use with the project as it is adopted by coroners within the state. |

1. ~~What Experience and qualifications does your company have in completing similar projects in terms of client, staff and achievements for software product development web-based platform and implementation.~~

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| Question was stricken from the RFP by IDOH. No answer provided. |

1. ~~What is your company’s experience with building and maintaining web based electronic platforms for the delivery of test results?~~

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| Question was stricken from the RFP by IDOH. No answer provided. |

1. What type of customer support services do you provide to your clients/customers/ users of the web-based electronic platform.

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| Axis’ service model provides direct access to a dedicated team of support professionals that assist users with the Axis Case Management Portal and the State’s custom file interfaces. The Portal team is accessible by telephone, email, and website form. Messages are addressed and resolved same day. Axis also provides a User Guide and onboarding training as needed.  The Case Management Portal is very intuitive to use for both retrieving final reports and checking case receipt and status. Axis tracks support requests from Case Management Portal users. 98% of requests are for assistance with usernames and passwords. Users rarely have questions regarding how to use the portal or about difficulty locating a case within the portal. |

1. Please provide Service Level Agreement for system support and maintenance plans of platform.

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| Axis provides a self-service option for password resets. During business hours, for lost usernames or other difficulties, the expected SLA is same day. Typical response is within two hours or less. The Case Management Portal is highly reliable and available. It requires very little maintenance and has virtually no downtime. The portal is a part of our Laboratory Information Management System, which is hosted and maintained by our vendor, Clinisys. Should downtime be required, the service window with our vendor is Saturday night between 2 and 6 am. A Case Management Portal outage would be of the highest level of SLA with our vendor. |

1. Describe how ongoing training and technical support is provided for the web-based electronic ~~delivery~~ platform?

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| Axis provides training, a user manual, and full technical support, as needed, for our Axis Case Management Portal. Our direct access service model allows users to contact a team of IT professionals directly to receive help with any and all technical issues with the Axis Case Management Portal.  Our support teams work closely together to ensure that, when Axis receives notification of personnel changes, to any of our support teams, the necessary updates and training occur to fully onboard the new personnel. User creation and deactivation is typically completed the same day the update is received. New users receive system-generated usernames and passwords upon account creation along with a copy of the user manual. Due to the intuitive nature of the Portal, most users require very little additional training, but the Portal team is prepared to assist as needed. |

1. What software security is implemented to protect system against malicious attacks, hackers, and other potential risks?

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| The Case Management Portal is very useful but it only allows users to obtain information, not to make any changes. It has standard web-based security protocols (https pages, unique usernames and passwords), as accessible to our user population. It is fully supported by our LIMS vendor, Clinsys, with whom we have routine bi-weekly ticket review meetings in addition to standard support. |

1. How regularly is the system upgraded with new versions for improvements, security, and technology upgrades?

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| The Case Management Portal, in its current iteration, was created in 2018. It has received minor updates when needs are identified, but there is not a specific upgrade schedule. The LIMS vendor ensures that the site meets current best practices for web security, including upgrades and patches to the underlying web architecture. These changes are typically invisible to the end user. |

1. Describe how change management and system patches are addressed?

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| When the need for a change is identified, it is built in a TEST environment which is a mirrored version of our Production environment but whose changes do not impact the Production environment. It is then subject to relevant test workflows to ensure that it performs as expected. Upon successful testing, it is applied to the Production environment, where it is again subject to test workflows to ensure proper functioning. |

1. Is code scanning done and what process is followed? How are flaws in data and security assessed and addressed?

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| Axis does not develop any code, and therefore, does not do any code scanning. The system that generates the results is protected behind firewalls, VPN tunnels and multi-factor authentication. |

1. Is there any security audit by any company as a part of annual security measure process?

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| Axis performs a cyber liability risk audit each year, which assesses Axis’ preparedness for security threats. Our LIMS vendor conducts a regular SOC3 audit, the current best practice for data center and cloud operations services systems. |

1. Describe how, or if, the web-based electronic platform ~~system~~ is compatible with mobile devices and tablets.

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| The Axis Case Management Portal is very simple but functional in its design, making it widely compatible with various device styles and operating systems. Strictly speaking, the commitment is to compatibility with desktop/laptop computers, but it functions effectively on small format devices, if desired. |

1. How is user authentication performed and can it be linked to Indiana Single Sign on Systems

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| User credentialing is maintained in our Laboratory Information Management System. Users can be requested and rescinded by contacting our Lab Client Support group. Single Sign-on is not available at this time. |

1. Do you provide a method for query access to the database for information that may not be available via standard reporting? Please describe capability.

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| We do not provide direct query access to our database for security and privacy reasons. The database contains information for all our clients and is not firewalled for external access. Query access could also compromise the performance of the system, as its structure requires extensive training to navigate.  To enable the State to manipulate its own data, one of the two interfaces developed between Axis and ISDH feeds the data into the Management Performance Hub. It is Axis’ understanding that querying of the information takes place there. We do not allow external access to our database. We aid with data structure and content questions when requested by the State.  We support the State’s epidemiology reporting. We work with the IDOH regarding utilization of the program. We have generated ad hoc reports to assess effective utilization of the program (not abusing the free testing provided by the State) and determined that 98% of the cases submitted are positive for one or more drugs. We discuss spending trends to aid in the management of the budget under the current agreement. We supplement the State’s reporting functionality when the County has specific targeted needs. As an example, Lake County needs a specific report regarding their xylazine cases that Axis provides to their specifications upon request. |

1. Do you provide a method for query access to the database for information that may not be available via standard reporting? Please describe capability.

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| This is a duplicate of question 27, response has been provided under question 27 above. |

1. What is your experience in establishing an interface with Public Health databases or similar clients databases?

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| In 2019, when Axis was awarded this contract, it committed to working with ISDH to establish automated reporting to two ISDH systems, the Coroner Case Management System and the Management Performance Hub. Both of these interfaces were completed in the agreed timeframe, and results were reported retroactively to the start of the contract to ensure that ISDH had complete data sets in both systems.  As personnel changes have occurred at the State level, Axis has assisted the new personnel in understanding the data and files that were requested. Should the State determine that changes needed to be made, with mutual agreement, Axis will assist in updating those platforms.  In addition to the capability described above, Axis also provides standard text-based, delimited file, and PDF-compatible interfaces with other death investigation software systems, and many clients can absorb the standard output for their internally developed systems.  Axis is an effective partner to State health departments. Axis collaborates with the external stakeholders to understand their needs and determine how best to transmit the case results to interface with their public health databases. Each group has specific files structures and formats to understand and transmission protocols and frequencies to capture. Ensuring robust intersystem authentication to allow for secure transmission is equally important to ensure timely transmittal of results. Axis willingly invests the development time involved with test files and security protocols and changing scope because we understand how important it is for serving our clients well.  Axis has developed multiple interfaces with the Commonwealth of Kentucky to provide both results and cause of death information that have caused them to be lauded by the CDC for the speed (less than two weeks) with which they are able to provide information.  We have also worked with NFLIS (National Forensic Laboratory Information System) to develop ways for clients to direct their results to that system as well. Axis does rely upon its LIMS vendor to develop customized interfaces, but it is a strong and effective working relationship as demonstrated when developing the two custom ISDH interfaces. |