

Empowering Global Health: Rapid Diagnostics in Infectious Disease Detection from Development to Implementation – Webinar Q&A

Empowering Global Health: Rapid Diagnostics in Infectious Disease Detection from Development webinar was held on May 13, 2025 in collaboration with Lateral Dx. Here is a comprehensive compilation of all the questions raised during the session, along with detailed answers provided by **Richard Campbell** from Lateral Dx and **Amy Moore** from Medix Biochemica.

1. When is the right time to test biospecimens in your assay development process?

Richard Campbell: As I mentioned in my presentation, including biospecimens in the development process is crucial. The main question is when to start using them. Typically, we begin with either a buffer matrix or a stripped serum—a kind of base or special matrix used for antibody screening. We then quickly confirm those results using analyte-spiked matrices or actual characterized samples.

I recommend including a small panel of around 10 well-characterized samples in your feasibility study. These should cover the range you aim to detect in your assay. As you progress, you can add more samples at each testing point. While biospecimens can be expensive, having a reasonable number early on can be very useful and save time later.

Short answer: aim for about 10 samples during the feasibility phase.

2. How many reagent lots should be tested to ensure robustness—and what exactly qualifies as a “lot”?

Richard Campbell: Typically, it's recommended to consider three batches of critical raw materials during the development process. While more batches would be beneficial, three is widely accepted as the industry standard for material lots.

Amy Moore: My experience also supports that three lots is the optimal number. Just to clarify, a lot or batch refers to a separate purification of material, where each batch must have strict traceability. This ensures that each lot can be traced back to its source—whether that's a specific supernatant, ascites, or recombinant expression batch.

Richard Campbell: I agree, especially since different manufacturers define a “lot” differently. You might think you're evaluating three separate lots from distinct starting materials, but in reality, they could be three separate purifications from the same source. That might still be acceptable—the key is the knowledge and information from your provider so you understand exactly what you're testing. That, to me, is the most important part.

3. Do you offer custom development solutions to meet unique customer needs?

Amy Moore: Yes, at Medix Biochemica we do, and we're very happy to co-develop or partner with any customer for recombinant antigens, negative antigens or antibodies.

Richard Campbell: Absolutely. At Lateral Dx, every project we do is a custom product—there's really nothing off the shelf. We tailor each development to the customer's specific requirements and the desired final test performance. While we follow similar processes, each development is generally customized to meet the customer's needs.

4. With so much attention on emerging outbreaks, how does your team respond to these urgent situations?

Amy Moore: At Medix Biochemica, all our production sites are purpose-built for IVD customers, allowing us to rapidly scale up production when needed. While forecasts are always helpful, we've successfully increased our capacity multiple times in response to urgent customer needs.

Richard Campbell: Exactly. When a new infectious disease emerges—or an existing one spreads or evolves—there's an urgent need to develop an effective test. Speed is critical. The first step is identifying the necessary reagents and antibodies. These may already exist or may need to be developed, with the latter naturally taking more time. Fortunately, advancements in recombinant technology are helping accelerate this process.

Once we have the components, we typically conduct proof-of-concept studies within 4 to 6 weeks. These provide valuable insights into test performance and operational feasibility. Within about three months, it's often possible to have a well-developed test ready for evaluation with clinical samples or user trials. That timeline is both realistic and practical.

Amy Moore: In addition, our R&D teams maintain a large development pipeline. If there's an outbreak requiring a product not listed in our catalog, there's a good chance it's already under development. We encourage customers to reach out and ask about ongoing developments or explore custom project opportunities with us.

Richard Campbell: Yes, Amy—we've done that before. You let us know certain products were already in the pipeline and offered pre-samples or trials. I would suggest that people should inquire about ongoing projects, as there are many developments that may be ready for evaluation.

5. You're working with some pretty scary stuff - has that changed how you go about things, either at work or in everyday life?

Amy Moore: I'm still doing some covid testing and using hand sanitizer more frequently than before the pandemic. As a microbiologist, I have always been conscious of what's around us and have healthy respect. However, I am neither paranoid nor nervous.

Richard Campbell: I'm similar. It raises your awareness. I'm unlikely to use a holiday rental hot tub unless it's thoroughly cleaned and tested. I won't take many additional precautions while traveling, but maybe I should. I often use lateral flow tests but understand their results require some knowledge.

6. Have you seen any increase in requests for development of lateral flow assays for nucleic acids (in combination with amplification or CRISPR) for emerging infectious diseases?

Richard Campbell: Most development do still use conventional reagents such as antibodies, however we are seeing an increase in requests for detection of nucleic acids coming from isothermal amplifications such as LAMP. For CRISPR there are some enquiries but customers should consider the patent situation around using this technology. It might be good for a research project but can you turn that into a commercial product?

7. How much time you take to develop a commercially viable lateral flow assay from the start of making antibodies?

Richard Campbell: For the Lateral flow development each Phase is approximately 3 months so for Feasibility, Optimisation and Transfer and Process validation that would be 12 months. This timeline can be shorter or longer depending on test complexity and regulatory requirements.

8. Which types of rapid diagnostic techniques are available, particularly for veterinary (zoonotic) parts, you hoped to deliver free?

Amy Moore: Please complete this survey: <https://survey-eu1.hsforms.com/1MiXm4FtOT4-M5jgvfzWeqgeuezy> and the Medix Biochemica team will contact you to discuss the available options.

9. How long will the development of a rapid lateral flow test take, approximately, from design till manufacturing?

Richard Campbell: As mentioned earlier, the full development process typically takes around 12 months.

Thank you for your active participation!

If you have any further questions or need additional clarification, feel free to reach out to us at medix@medixbiochemica.com

View the webinar on demand at:

medixbiochemica.com/rapid-diagnostics-in-infectious-disease-webinar

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