Guest Consultant Libby Knollmeyer: “I think I want a lab for my office!”

While there are multiple levels of laboratory complexity, it is possible to have a lab in your practice with very little fuss and administrative burden. The level of complexity of any lab is determined by the testing being performed, and the complexity level of each test or test system is assigned by the FDA.

What is Waived Testing?

The **Waived** category allows physicians to do simple testing in their offices to facilitate diagnosis and enhance patient care with on-the-spot results. A test or test kit gets classified as Waived if it:

- is extremely easy to perform
- has built-in safeguards, and
- requires little education or training to do and interpret correctly.

Urine dipsticks, **rapid Strep A kits**, **urine pregnancy test kits**, and **rapid Mono Test kits** are examples of waived tests. In addition, there are also some Point of Care (POC or POCT) tests/instruments that have been granted waived status, including **glucose monitors** and **hemoglobin instruments**. There is a wide variety of testing available to the practitioner without having to bear the administrative burdens of the moderate or high complexity laboratory.

Of the various types of laboratories defined, the Waived lab has the least regulatory oversight. CLIA does not have personnel requirements for Waived labs other than requiring there be a lab director, which any physician in the practice

can fulfill. It is common for the lab director to receive a monthly stipend of $300 – $500 per month for fulfilling this simple role.

The only regulations that apply to waived testing are:

- requirement to have a CLIA ID # and pay the Certificate Fee every two years, and
- to follow the manufacturer's instructions for any test performed.

Laboratories are not required to subscribe to Proficiency Testing for waived tests, and there is generally no inspection of waived laboratories every two years as there is for moderately and highly complex labs. CLIA has the right to come in and inspect at any time, and they are trying to inspect about 2% of the waived labs each year. Generally, though, they are short-staffed and these waived lab inspections are not the priority that the more complex labs are unless there has been a complaint filed.

What does "Following Manufacturer's Requirements/Recommendations" mean?

"Following Manufacturer's Requirements/Recommendations" means following all the instructions that come with the test kit in the form of a package insert. This insert will include instructions on Quality Control, how to perform the test, interpretation of the test results, and environmental conditions suitable for performing the test. Because there are usually temperature requirements for storage of the tests and for performing them, refrigerator temperatures and room temperature will need to be monitored and recorded each day of testing. See my post on lab refrigeration **here**. If the package insert includes humidity specifications, then room humidity will need to be monitored and recorded also. Hardware stores and medical supply companies both sell devices for measuring the temperature and humidity of a room. The device hangs on a

wall and is frequently a digital read-out, but some are dial read-outs.

I want to start with dipstick urine tests in my practice – how do I accomplish this?

Start by submitting an application to CMS for a CLIA certificate. This is done by filling out the CMS116 form and mailing it to the CLIA office in your state. **Click here** to go to an interactive version of the application form that can be filled out electronically. It is 4 pages in length, and following Page 4 are detailed instructions for how to complete it. It must be printed out and signed and dated by your Lab Director before mailing it to the CLIA Certification Office in your state – no money needs to be included for the CMS116 application. **Here is a list** of CLIA offices by state. In most states it takes 30-45 days to obtain a CLIA ID number and certificate. Please note that some states have state laboratory regulations in addition to CLIA laboratory regulations and most of these states require state licensure of laboratories in addition to the CLIA Certificate. While CLIA does not require money be submitted with the CMS116 application, state applications often do require that money be submitted along with the initial application. Be sure to check with your state to determine if this is the case where you are located.

Once the CLIA Certificate and ID number have been issued (and any state licensure completed if required) you are free to begin testing. At some point you will receive a bill from CMS for the CLIA Certificate Fee. Don’t overlook this because failure to pay it will inactivate your CLIA ID number.

Competency Testing

Now you will identify and train the personnel who will perform

the testing. Almost anyone in your office can do this once you have them pass a urine dip competency which will include:

1. **Performing controls**. Control materials for urine dips are purchased separately and dipped as though they were a patient specimen. Two levels (negative and positive) are tested, but most manufacturers only require Quality Control (QC) when a new lot number is opened or a new shipment (even if the same lot number) is received.
2. **Patient Communication.** Explaining to the patient the instructions for providing a urine sample. Although many offices provide written instructions in the rest room, remember that not all patients read well or read English.
3. **Timing the test.**
4. **Recording results** – I recommend having a log sheet that has a place for the patient i.d. and results for each analyte on the strip. Another alternative is to get an automated strip reader, which can can be obtained without purchasing it if enough vials of test strips are purchased. This has a printed report that is generated and also standardizes the reading so variations from one person to another don't play a part in results.
5. **Cleaning** after each test, and and documenting daily cleaning on a log sheet.

Finally…

purchase the test strips (almost all medical/surgical supply vendors carry waived testing kits and strips), and develop a mechanism to get the results to the provider (entry into an EMR or paper chart or via a paper document). You will need a little space on a counter somewhere, preferably close to a sink, and good light to read the strip under. Urine is not considered a biohazardous material unless it is contains visible pus or blood, so disposal of the urine when testing is complete is easy—pour it down the sink or flush it down a

toilet.

And *voila! Y*ou have a lab.

Consultant Elizabeth “Libby” Knollmeyer, B.S., MT (ASCP) has over 40 years experience in the laboratory industry and has set up many laboratories! She specializes in financial, operational management and compliance issues for both hospital and physician office laboratories. Libby has a wide variety of experience with her areas of special expertise including financial review and management, Quality Management protocols, Outreach development, compliance and regulatory assistance, lab design and up fitting, lab remodeling, and market research for IVD manufacturers. She works independently and with large consulting groups to provide interim management for hospitals, and serves as adviser to lab equipment and supply distributors. She consults (and enjoys traveling) throughout the US and internationally. She can be reached at (336) 288-5823 or at eknollmeyer@triad.rr.com.