Kit Tests

Many diseases and conditions can be detected in the laboratory with the use of specific, small, self-contained kits. The kits typically contain all reagents necessary to perform the test, as well as disposables such as test cards and stirring sticks.

Most kits test for the presence of a particular substance, such as hCG, that uses an antibody to the substance which is attached to a dye. If the substance is present, the dye changes colors, indicating a positive reaction.

When you receive a kit, such as a rapid Strep, label it with the date received. You will want to use the oldest kit first. Then date the kit when brought to room temperature before use, and adjust the expiration date if necessary. The lot number and the date opened for use can be documented in the quality control logs for the appropriate kit test.

It is important to read the instructions for proper storage and expected shelf life of the kit. Store all kits according to manufacturer's instructions. Different components of a kit may have different storage requirements.

Reagents, once reconstituted, may expire before the expiration date printed on the kit. Outdated kits should not be used. Discard the entire kit when any component of the kit has reached its expiration date. Discard the outdated kit as outlined by the manufacturer's package insert or as indicated in the laboratory's policy for disposal of outdated materials.

Kit shelf life may depend on whether the kit is stored in the refrigerator or at room temperature. In general, the shelf life of a kit is longer when stored in the refrigerator. Be sure to check your kit's instructions to determine if room temperature storage will shorten the expiration date.

Follow the manufacturer's instructions for the proper use of the kit. Read the package insert carefully each time a new lot is received and take note of any changes in quality control, reagent preparation, and storage requirements.

This is especially important when changing brands of kits. The number of drops and sequence of reagent additions, as well as the number of reagents will likely differ from kit to kit. Also, the timing between each step and reading the final results varies from one manufacturer to another.

Reagents from a kit test should only be used with that kit. The only exception to this is when the manufacturer's instructions specify that it is permissible to mix reagents from different kits with the same lot number. Never mix reagents from one kit test to another with a different lot number, or components from different manufacturers. Any of the above practices can cause erroneous results.

Each diagnostic kit product should have its own package insert placed in the laboratory's procedure manual. Because a laboratory may try new kits from a variety of manufacturers, retain the insert for the current kit in use in the procedure manual. Date the old one and place it with your discontinued procedures. Keep your discontinued procedures for at least two years.

QUALITY CONTROL

Most kit tests include controls. There are two types of controls. Procedural controls are those which are built into the membrane pads of the kit and will appear as a specific color and shape at the completion of the test to indicate the kit is functioning as expected. The other type consists of a positive and negative liquid control material.

Unless the manufacturer requires external liquid controls be performed when opening the kit, those with built-in procedural control systems satisfy the requirement for quality control for unmodified moderate complexity tests. When performing patient testing, document at least once per testing day that the built-in controls have reacted as expected. The control values may be recorded with the patient test report or in the quality control log for each test.

For kits that do not have procedural controls, test positive and negative liquid controls with each batch of patient tests. A batch of patient tests may be all those patients run during a period not to exceed 24 hours. The controls must demonstrate appropriate reactivity before patient results are reported.

If you use immunology kit tests that rely on agglutination or precipitation of latex or cells, run a positive and negative control solution with each batch of patient tests. Record all control values in the quality control

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log for each test. You may record the values as either +/- or positive/negative. For immunology kit tests which require titering, run a positive control of known titer and a negative control with each batch of patient specimens. Be sure to record the titer of the control specimen in the appropriate quality control log.

Take corrective action if the kit test controls fail to react appropriately. Do not report patient test results until the controls react as expected. Document the quality control results and include the following:

- Kit and quality control lot numbers
- Control results (including any repeated control results)
- Corrective action where applicable
- Date performed
- Initials of the person who performed the test

Read the kit package insert for additional information relating to quality control. You may also refer to questions 210-212 in Tab IV, Criteria for Quality Laboratory Performance in the *COLA Accreditation Manual* or call the COLA Information Resource Center at (800) 981-9883.

PROFICIENCY TESTING

Many analytes detected by kit tests are regulated and, therefore, enrollment in a COLA approved proficiency testing (PT) program is required. Ask your PT program which tests on your test menu require PT enrollment. PT samples will be sent three times a year and you will need to report these results back to your PT company.

For further details on PT, see COLA LabFacts 8 *Proficiency Testing*.