IBT Bulletin

2931 Moose Trail, Elkhart, IN 46514
1-800-490-5500 Fax: 574-264-2787

Quality Control of the Reagent Strips

The terms Quality Assurance and Quality Control are often used interchangeably. However, Quality Assurance (QA) usually encompass much wider scope including all aspects of manufacturing processes which lead to the quality of the products. Quality Control (QC) usually refers to the testing or measurement of a specific parameter of the product to assure consistency of the production process or the product quality. All medical devices manufactured in the United States are required by law to maintain a stringent Quality Assurance Program or a Quality Management System which follows the recommended guidelines of the Good Manufacturing Practice (GMP) laid out by the US Federal Drug and Food Administration (FDA). When a product is manufactured in accordance with the GMP guideline, the process is in conformance with the US FDA quality regulatory requirements.

Should the end user of the strips perform the QC test before using the products ?
Yes, it is highly recommended. As part of the Quality System Requirement, all products are tested before released for marketing. However, for those products such as reagent test strips whose performance can be affected by storage temperature, lighting and humidity, the state of the product quality may change after leaving the manufacturers if the product is not properly handled. It is therefore highly recommended that the end user of the products to perform a simplified quality control (QC) test to assure that the performance of the products still fall within the specifications.

Other important reason for performing the quality control test by the end user is to verify that the strip is the correct strip as labeled. Many test strips look alike when it is removed from the container. Misuse of the strip may cause erroneous results which could cause serious harm to patients. A QC test with a proper control solution will help to assure that there is no mislabeling of the products. As part of the Quality Program, all the critical test strips manufactured by IBT carry a product identity mark on each strips. For example, the WaterCheck 2, low level chlorine/chloramine test strip, will have a marking of CM on each one of the strips and, the WaterCheck RC, residual chlorine test strip, will have a marking of RC on the strips. For those strips with distinctly recognizable color, there will have a marking of IBT on the strip to provide traceability to the manufacturer.

What control solution should be used.
One main criteria of the QC solution is that the test should mimic the actual reaction of the strip test. First, the level of the control solution should be within the testing range of the strip. Second, the chemical in the QC solution should react with the key component of the reagent in the strips. Third, the testing procedure should be similar to the procedure recommended for the strip test. Some of the strips may react to a common chemical. For example, both the chlorine and peroxide test strips will react to a common oxidant, but with different degree of reactivity. It is important to use only the QC solution designed and recommended for the specific strip.

The QC solution can be prepared from the actual solution to be tested. The detailed procedure for dilution and the preparation of the solution usually can be fond in the product insert. In some cases, the QC control material is provided with the strip product. Usually only a simple procedure is required to prepare the working solution.

Since the QC solutions prepared on site usually are not as accurate as the standard solutions prepared in the laboratory, the results of the QC test will fall within certain range.

How often should the QC test be run ?
The strips are manufactured in batch from a single roll of paper. There is practically no difference in the strip reactivity from bottle to bottle. It is not necessary to perform QC test on each bottle within the same lot. Only one of the six bottles in the box needs to be tested with both a positive and negative control. However, if the bottle is within three months of the expiration date, additional QC tests may be necessary.

How long the strip is good after the bottle is opened ?
Answer to the question depends on the type of the strip and how the strip is used. Under normal use and if the bottle is remained tightly capped, the strip should be stable for at least 3 months. However, the user should always be aware that the strip could go bad before 3 month self life if the strip is not properly handled, or it could remain stable after three months. There is no clean cut shelf life of the strip once the bottle is opened. If the test result is outside of the expected value, additional QC tests may be necessary to determine the condition of the strip and whether or not the strip can continued be used.

The recommended open shelf life for oxidation based strips, chlorine/chloramine, peroxide or blood hemoglobin, is 3 months. For pH and water hardness strips, the open shelf life can be extended to 4 months. One unique feature about the chlorine/chloramine or peroxide test strips is that they will always show a trace of green if there is a deterioration of the strips. Therefore, if the strip is tested negative with a DI water, it by itself is a valid QC test, indicating that the strip is stable and may be used. *Ic*