



Calibration Test Place Recertification Interval

BioTek's Calibration Test Plates are utilized to ensure that microplate readers are functioning properly without periodic calibration of the latter. Through this use the Calibration Test Plates are designated as "check standards" (see NOTE 1).

Per Z540-1 † section 18.4 "Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically."

The neutral density glass filters utilized in the Calibration Test Plates are normally very stable. They can, however, be altered by fumes from laboratory etching agents, such as acids or bases or by excessive exposure to UV light. Etching of the glass would allow unwanted diffraction of light thereby changing the Optical Density (OD) values, UV light could change the physical composition of the glass with a similar effect. Additionally, lint, dust or smudges on the glass can also alter the OD value.

The Calibration Test Plates also have precision mechanical alignment holes, the location of which could be altered if the Plate is dropped and deformation occurs. The operation of the alignment holes can also be impaired by lint or other debris in them.

Due to these two possible deviation sources a one year recertification cycle has been selected for the Calibration Test Plates. The one year cycle is based on our present experience with returned plates and is based on the Z540-1 section 18.4 † "Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained." BioTek's goal is that all Calibration Test Plates that are returned for recertification meet all of the original specifications.

As to the need to apply a calibration sticker the end user must have some easy way to verify the status of the Plate's calibration. This requirement can be found in section 18.10 of Z540-1 † "M&TE shall be labeled to indicate calibration or verification status."

NOTE 1: Per Z540-1 section 18.4 † "Intervals shall be established for all M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process." Thus, if the Calibration Test Plate, or a similar method of "check standard" is not utilized, the reader's performance criteria must be verified through a documented calibration program.

Reference: † ANSI/NCSL Z540-1-1994 "Calibration Laboratories and Measuring and Test Equipment - General Requirements"