Designation: E1093 – 91 (Reapproved 2012)

Standard Specification for Glass Prothrombin Pipet, Disposable[1]

This standard is issued under the fixed designation E1093; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers a glass disposable Prothrombin pipet suitable for use in micro techniques for estimation of Prothrombin time.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 This precautionary statement pertains only to the test method portion, Section 8, of this specification.*This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]
E438 Specification for Glasses in Laboratory Apparatus
2.2 *ISO Standard:*[3]
1769 Laboratory Glassware—Pipettes—Color Coding

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*
3.1.1 *accuracy*—the expected distribution of mean volumes around the stated volume.

3.1.2 *coefficient of variation*—the expected distribution of individual volumes around the mean volume.

3.1.3 *disposable*—Prothrombin pipets which are intended to be used once only and then discarded.

NOTE 1—Such pipets will only be expected to provide their specified performance during the original operation.

4. Classification

4.1 This specification covers only one glass pipet as illustrated in Fig. X1.1.

5. Materials and Manufacture

5.1 The pipet shall be made of borosilicate glass, Type 1; Class B, or soda lime glass, Type 2, in accordance with Specification E438.

6. Physical Properties

6.1 *Design*—The Prothrombin pipet shall be made of one piece construction glass tubing that is straight and with uniform bore and lightly firepolished on both ends. The pipet shall be made to the dimensions as specified in Fig. X1.1.

6.2 *Dimensions*—The pipet shall be made of tubing with a minimum outside diameter (o.d.) of 2.3 mm with an inside diameter (i.d.) of 1.7 mm. The uniformity of the bore shall be ±0.05 mm throughout the straight portion of the pipet. The pipet shall be a minimum of 160 mm long.

6.3 *Capacity*—The pipet shall be calibrated "to deliver" (T.D.) 0.1 and 0.2 mL at 20°C. Marking shall be as specified in 6.5.

6.3.1 *Accuracy* (see 3.1.1)—The accuracy from stated volume shall be ±2.0 % for the 0.1 and 0.2-mL capacity and shall be determined as specified in 8.1.

6.3.2 *Coefficient of Variation* (see 3.1.2)—The coefficient of variation from stated volume for the 0.1 and 0.2-mL capacity shall not exceed 2.0 % and shall be determined as specified in 8.1.

6.4 *Graduation Lines*—The pipet shall be calibrated and marked with graduation lines at 0.1 and 0.2 mL from the tip of the pipet. The graduation lines shall be 0.3 ± 0.1 mm and shall completely encircle the tube.

6.5 *Pipet Nomenclature*—The pipet shall be marked with 0.1 and 0.2-mL markings slightly above the graduation lines. The pipet may be marked with the inscription T.D. 20°C, or the manufacturer's or vendor's name or trademark, or both.

6.6 *Blow-out Delivery*—The Prothrombin pipet is designed as a dual delivery system for the determinations of coagulation assays. When utilizing the 0.2 mL calibration line, the tip of the pipet should contact the wall of the receiving vessel and allow the pipet to drain freely. The remaining quantity of liquid is to

[1] This specification is under the jurisdiction of ASTM Committee E41 on Laboratory Apparatus and is the direct responsibility of Subcommittee E41.01 on Apparatus.

Current edition approved Nov. 1, 2012. Published November 2012. Originally approved in 1986. Last previous edition approved in 2005 as E1093 – 91 (2005). DOI: 10.1520/E1093-91R12.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from ISO, 1 Rue de Varembe, Case Postal 56, Crt 1221, Geneva 20, Switzerland.

be blown out into the center of the receiving vessel. When utilizing the 0.1 mL calibration line the contents are to be vigorously blown out into the center of the receiving vessel with one quick effort. Either one band or two narrow bands shall encircle the top end of the pipet to signify the contents must be blown out as shown in Fig. X1.1.

6.7 *Color Coding*—The pipet shall be color coded for capacity as specified in ISO Standard 1769 with an "orange" color band that is 6 ± 2 mm wide and located 16 ± 2 mm from the top of the pipet as shown in Fig. X1.1.

6.8 *Marking Permanency*—Graduation lines, inscriptions, and numerical markings on the pipet (other than the color code band) shall be black in color. All markings may not be of permanent nature but must possess sufficient stability to endure normal transportation and its expected one-time use and must meet the test requirements as specified in 8.5.

6.9 *Lot Control*—A lot or control number shall be indicated on the pipet container package. This lot or control number shall be traceable to the origin and purchase order of raw material glass tubing.

7. Workmanship, Finish, and Appearance

7.1 The pipet shall be as free as possible of visible defects which would detract from its appearance or impair its serviceability when viewed by the human eye under normal room lighting.

8. Test Method

8.1 *Capacity:*

8.1.1 *Weighing Volume, Using Water*—Allow a small vessel (5-mL beaker) and a container of distilled water to stand at room temperature of 20 to 25°C for 2 h. Weigh the dry vessel and record the weight. Fill the pipet with water and adjust to the calibration line. Deliver the contents of the pipet in the prescribed manner into the vessel. Reweigh the vessel with water content and record the weight. Record the room temperature. Subtract the recorded weight of the dry vessel from the recorded weight of the water-containing vessel to obtain the apparent mass of the contained water. Calculate the volume, *V*, in accordance with the appendix.

NOTE 2—To accurately perform this test method, the reliability of the weighing instrument used should be confirmed against a known standard and the weighing instrument should possess a minimum sensitivity of 0.01 mg.

8.2 *Calculation*—Calculate the volume, *V*, of a micropipet from the weighings, in air, as follows:

$$V = W \times Z \quad (1)$$

where:

W = apparent mass of liquid (water), weighed in air, and
Z = apparent specific volume of liquid (water).

Values of *Z* for water are given in the appendix.

8.3 *Capacity Deviation* (single pipet)—In accordance with the methods outlined, capacity deviation is the difference between the stated capacity and the observed capacity of the pipet as follows:

$$\text{Capacity deviations, \%} = (V_c - V_1) \times 100/V_1 \quad (2)$$

$$V_c = V_t/1 + a(t - 20°C) \quad (3)$$

where:

V_t = observed volumetric capacity at t°C, uL,
V_c = corrected volumetric capacity at 20°C, uL,
a = coefficient of cubical expansion of pipet glass equals 0.000010/°C for Type 1, Class A (borosilicate); 0.000015/°C for Type 1, Class B (noncorrosive borosilicate); and 0.000025/°C for Type 2 (soda-lime),
V_1 = stated capacity of pipet, uL, and
t = temperature, °C.

8.4 *Capacity Deviation* (number of pipets)—Test a minimum of 30 pipets taken at random from a completed manufactured production lot. Calculate the volumetric deviation for the 30 pipets as follows:

8.4.1 *Accuracy:*

$$\text{Accuracy, \%} = 100(\bar{x} - V_1)/V_1$$

where:

$\bar{x}$ = mean of sample measurements, and
V_1 = stated capacity of pipet.

8.4.2 *Coefficient of Variation:*

$$\text{Coefficent of variation, \%} = 100s/\bar{x}\ s = \sqrt{(x - \bar{x})^2\, n - 1} \quad (4)$$

where:

x = individual sample measurement,
$\bar{x}$ = mean of sample measurements, and
n = number of pipets measured.

8.5 *Pipet Marking Permanency Test*—Immerse the tube in distilled water for 30 s. Using a soft paper tissue, wipe the marked portion of the pipet lightly with ten complete strokes (five up and five down). When judged by the naked eye under normal room lighting the pipet markings should appear as before the test with only possible lightening of the markings or minor removal of the markings, or both, that would not effect the pipets serviceability.

9. Keywords

9.1 disposable; glass; pipet; Prothrombin

APPENDIX

(Nonmandatory Information)

X1. See Table X1.1 and Fig. X1.1.

TABLE X1.1 Density and Z Factor for Water

Temperature, °C	Density, g/cm^3	Z, cm^3 /g
20	0.99820	1.0029
21	0.99799	1.0031
22	0.99777	1.0033
23	0.99754	1.0035
24	0.99729	1.0037
25	0.99704	1.0040
26	0.99678	1.0042
27	0.99651	1.0045
28	0.99623	1.0047
29	0.99594	1.0051
30	0.99564	1.0054

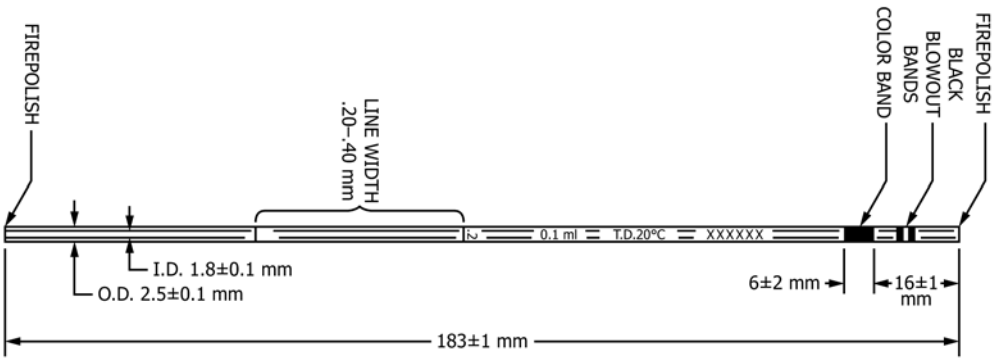

FIG. X1.1 Glass Prothrombin Pipet, Disposable