

## *Quantab Accuracy Statement*

Our QA personnel have a well-documented procedure for testing each lot of Quantabs. They first construct a calibration curve by developing ten Quantabs for each of either five or six levels of sodium chloride concentration. Data for each level must show a standard deviation of 0.2 Quantab Units (2% of the scale of 10 on the titrator) or less. New test solutions are prepared for the testing of four "accuracy levels" of sodium chloride. Each of the "accuracy levels" is tested with nine titrators selected at random from the lot. The average of the nine values must be within 10% of the standard value (from the calibration curve). If the latter test fails at a particular sodium chloride level, six Quantabs are sampled from each of six locations within the lot, and all 36 titrators are used to test the failing level. The average of the 36 results must be within 10% of the standard value. The job of the QA people is to be sure that lots failing either of the above tests do not ship. There is also a brief testing step for the chemically impregnated paper before it is laminated and made into Quantabs. Thus, ETS certifies an accuracy of +/- 10% for the Quantabs. Precision could be inferred from the required standard deviation for each sodium chloride level of the calibration data (0.20 Quantab Units). The percent sodium chloride vs. Quantab Units curve is not linear, and a given variation in Quantab units corresponds to a greater variation in percent sodium chloride at the high end of the scale compared with the low end. From the appearance of the plot, the precision expressed as a fraction (standard deviation over percent sodium chloride value) seems not to vary much from about +/- 10%. There are additional specifications ensuring that the Quantab peak has an acceptable appearance and that the lamination is of good quality.