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Bion Analytical Statement of Quality – Analytical Standards and Reference Materials

1. Stock Reagent Purity

Bion purchases the highest purity reagents available for its Analytical Standards and Reference Materials. Since most reagents are not available with purities of 100%, the mass used in the preparation is corrected in accordance with the stated purity level for each reagent used, thus ensuring an accurate concentration for each analyte. Additionally, all stock reagents are stored in a tightly controlled environment to ensure the prevention of any degradation or moisture absorption.

2. Preparation

All of Bion's Analytical Standards and Reference Materials are prepared by gravimetric documented addition. The balances used in the preparation stage are validated with NIST Traceable weights, which cover the entire range of the balance, before and after all preparation activities. In this manner, the balances used for preparation activities and the masses measured for each component in a given Analytical Standard or Reference Material, are bracketed by a NIST weight verification process. The results for these balance validation procedures are documented and are traceable to each Lot produced. Likewise, the mass of each component added is documented and is traceable to each Lot produced.

The process of gravimetric documented addition is the most reliable way to guarantee component concentration in an Analytical Standard or Reference Material. Any subsequent quantitative instrument measurement performed on an Analytical Standard or Reference Material is inferior to gravimetric documented addition by virtue of two factors:

2.1 Measurement/Method Error

2.1.1 Instrument Error

All quantitative instrument measurements are subject to error. Measurements, therefore, that depend on the use of analytical instruments will have error introduced during the measurement process. Whether the error is random or systematic is a lengthier and different discussion, but all measurement devices will introduce some level of error into the result generated.

2.1.2 Analyst Error

All measurements are also subject to error introduced by the analyst (i.e. human error). Like with instrument error, this error can be random or systematic, but under no circumstances can it be avoided. All measurements depend on some level of human interaction thereby subjecting it to the inevitable introduction of error.

2.2 Calibration Accuracy

Additionally, quantitative instrument measurements are inferior to gravimetric documented addition for verification of analyte concentration by nature of the fact that the quantitative measurement used is typically based on a calibration, thus bringing into question the accuracy of that analytical standard used for calibration. Until one reaches a gravimetric foundation, it becomes a perpetual process of attempting to trace back to the accuracy of the standard used for calibration.

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For all the reasons discussed above, quantitative instrument measurements are not adequate replacements for gravimetric documented addition for the verification of analyte concentrations in Analytical Standards and/or Reference Materials. While gravimetric addition is a type of quantitative technique and thereby also susceptible to the error discussed above, the error introduced in the gravimetric addition process is typically much less than that introduced by other secondary quantitative instrument measurements. Additionally, because Analytical Standards and Reference Materials must be prepared either by mass or volume (all Bion's are prepared by mass because measuring by mass introduces less error than by volume), the process of gravimetric (or volumetric) addition cannot be eliminated – by nature one is required; therefore, the use of other quantitative instrument measurements only serves to add to the already unavoidable error.

3. Certification

All Bion's Analytical Standards and Reference Materials are also certified by the gravimetric documented addition procedure. Certificates of Guarantee are available for all Analytical Standards and Reference Materials produced by Bion. For the reasons discussed in the preceding section, the Certificate of Guarantee is superior to a Certificate of Analysis. Certificates of Analysis state analyte concentrations based on a measured value generated by a secondary quantitative instrument measurement while Certificates of Guarantee state analyte concentrations based on the gravimetric documented addition process. Each of the Certificates of Guarantee that Bion issues states both the analyte concentration and the respective uncertainty. This uncertainty is the summation of the maximum error that could be introduced during the production process, the majority of which is attributed to the certified error level of the balances used. The CoG, thereby, represents the ***production guarantee*** for each Analytical Standard and Reference Material produced.

As previously discussed, all quantitative instrument measurements performed on any Analytical Standard or Reference Material will always experience some level of variation, as error in measurement is unavoidable. For this reason the acceptable ***control limits*** used by any laboratory using the Analytical Standards or Reference Materials prepared by Bion will always need to be greater than the production guarantee that is referenced on the CoG. The production guarantee (stated on the CoG and based on gravimetric documented addition) will always be more stringent than any one instrument could hope to achieve consistently due to the inherent error of the measurement experienced. It is important to remember that it is the Analytical Standard that is used to judge the performance of the instrument, not the other way around. The unavoidable and inherent error experienced in instrument measurements is the reason laboratories need Analytical Standards - to determine if the instrument is returning values that can be trusted. Laboratories should establish control limits for the respective methods and instruments that are used. These control limits should be established based on the capability of the method/instrument and take into account the total error that can be expected from 1) the Analytical Standard and Reference Material (i.e. the CoG uncertainties) **plus** 2) the instrument and analyst error (i.e. measurement error). The CoG guarantee only quantifies the error of the individual analytes in the Analytical Standard or Reference Material contributed solely from the preparation process. For these reasons a laboratory should not expect to have a method and/or instrument return values on an Analytical Standard or Reference Material that consistently meet the CoG uncertainties since the additional error introduced from the use of the Analytical Standard or Reference Material will make the CoG uncertainties unattainable as control limits.

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In all instances Bion does use quantitative instrument measurements to do an additional verification of component concentration and homogeneity for all its Analytical Standards and Reference Materials; however, these measurements are used only as a secondary check. In all cases Bion's guarantee is based on the superior process of gravimetric documented addition. Gravimetric documented addition is the only true plumb line for the preparation of Analytical Standards and Reference Materials.

4. Expiration Date

Every Analytical Standard and Reference Material produced by Bion includes an Expiration Date. The stated Expiration Date on each product is determined by evaluating two aspects of the respective Analytical Standard or Reference Material: 1) Shelf Life and 2) Practical Usable Life.

4.1 Shelf life

The shelf life of an Analytical Standard or Reference Material is defined as the amount of time the product can be expected to be within its production guarantee (i.e. the values and related uncertainties stated on the Certificate of Guarantee). The shelf life of the product is based on studies that maintain the product at prescribed storage conditions with the product remaining unopened during the time of the evaluation.

4.2 Practical Usable Life

The practical usable life of an Analytical Standard or Reference Material is defined as the length of time one can expect to use the material and still be confident it will be within its production guarantee (i.e. the values and related uncertainties stated on the Certificate of Guarantee) and thereby return a value upon use that is within the laboratories control limits. The key distinction here is that the material is being used during the time, not stored unopened. Many factors impact the practical usable life, such as: contamination potential, analyst aliquot techniques, volatile loss, frequent temperature changes, and frequent opening of the material container, just to name a few. While it is practically impossible to quantify the combined impact of the myriad of potential practices that could compromise the integrity of the Analytical Standard or Reference Material once it gets into the hands of the various laboratory personnel using the materials, it is certain that the collective errors introduced once the container is opened will serve to reduce the time one can be confident in the accuracy of the Analytical Standard or Reference Material.

The Expiration Date stated on the container is thereby established by evaluating the Shelf life and then reducing that time by taking into account the factors contributing to the Practical Usable Life. The Shelf Life is considered to be the maximum amount of time one could expect the product to remain accurate to its stated analyte concentrations. The Expiration Date tempers that amount of time with the fact that regular use of the product will likely truncate the amount of time one could be confident the material still meets its stated guarantee. Rather than print multiple dates on its Analytical Standards and Reference Materials, a practice that is likely to be confusing for customers, Bion has chosen to simply post an Expiration Date. If the Analytical Standard or Reference Material is stored as prescribed and remains unopened in the customer's laboratory, one could expect to be able to use the product for slightly longer than the Expiration Date states; however, Bion's guarantee of analyte concentrations only applies for the duration of the Expiration Date.