510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k100750

B. Purpose for Submission:

To obtain a substantial equivalence determination for this original application for the Audit™ MicroCV™ Anti-streptolysin O (ASO) Linearity Set.

C. Measurand:

Anti-strepotlysin O (ASO).

D. Type of Test:

Calibrators and Controls.

E. Applicant:

Alto Scientific, Ltd.

F. Proprietary and Established Names:

Audit™ Micro CV™ ASO Linearity Set

ASO Linearity Set

G. Regulatory Information:

1. Regulation section:

   862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

   Class I

3. Product code:

   MJX

4. Panel:

   Microbiology

H. Intended Use:

1. Intended use(s):

   Audit™ Micro CV™ ASO Linearity Set is assayed quality control material consisting of five levels of Anti-streptolysin O (ASO) analyte prepared in human based serum. The five levels demonstrate a linear relationship to each other. It is intended to simulate human patient serum samples for purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Anti-streptolysin O. This product may be used as an unassayed quality control material for Anti-streptolysin O (ASO) analyte.

2. Indication(s) for use:

   The Audit™ MicroCV™ ASO Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains Anti-streptolysin O (ASO) analyte. The five levels demonstrate a linear relationship to each other for Anti-streptolysin O (ASO) analyte. It is intended to simulate human patient serum samples for purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Anti-streptolysin O (ASO). This product may be used as unassayed quality control material for Anti-streptolysin O (ASO) analyte.

3. Special conditions for use statement(s):

   Prescription use only.

4. Special instrument requirements:

   Beckman Coulter IMMAGE® Immunochemistry System

I. Device Description:

The Audit™ MicroCV™ ASO Linearity Set is a human based, liquid, five level set of QC material, with each level containing one analyte: Anti-streptolysin O (ASO). It is used to confirm the proper calibration, linear operating range, and reportable range of ASO. Level A has concentration near the lower limit level and Level E has concentrations near the upper limit level of instruments. Levels B – D are related by linear dilution of Level A and Level E.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Audit™ MicroCV™ General Chemistry Linearity Set

2. Predicate K number(s):

   k042318

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Linear, calibration verification quality control material	Same
Number of levels per vial	5	Same
Contents	5X 1 mL	Same
Matrix	Human based serum	Same
Sterile	Yes	Same

Differences		
Item	Device	Predicate
Number of analytes per vial	1	30
Type of Analyte	Anti-streptolysin O (ASO)	General Chemistry
Form	Liquid	Freeze dried
Preservatives	Sorbitol, Sucrose, Sodium Azide	Sorbitol, Sodium Azide
Open vial stability	24 hours at 2-8º C	7 days at 2 to 8º C except for enzymes and bilirubin, which are 48 hours

K. Standard/Guidance Document Referenced (if applicable):

Not Applicable.

L. Test Principle:

Laboratories use a stable reference material to verify the accuracy and precision of testing methods and techniques. Audit® MicroCV™ ASO Linearity Set may be used as one would use human serum to verify and validate the test method analytical measurement range.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable.

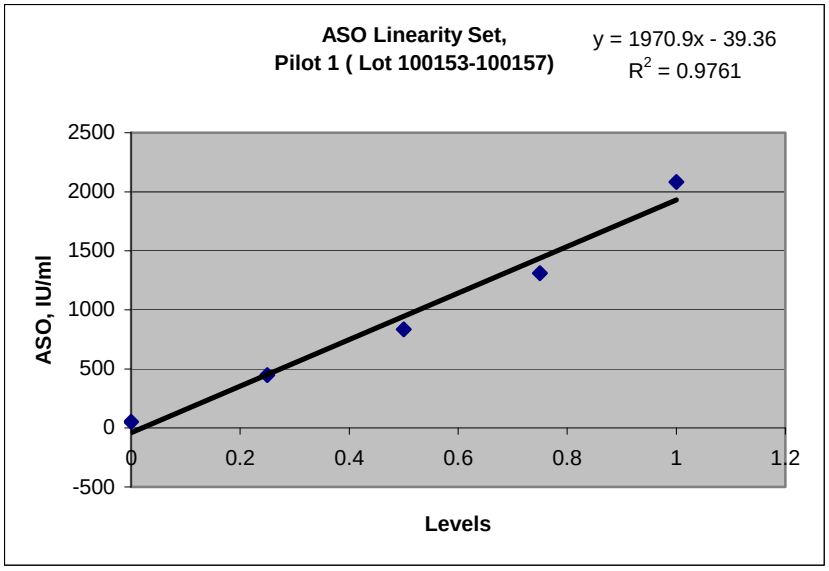
b. Linearity/assay reportable range:

Value assignment for each level was based on ten results. Target values were calculated from mean values of the ten results for each level. Assigned target values were graphed and a linear regression value was obtained to determine linearity of the five levels. The ASO five level set demonstrates a linear relationship for their respective analyte levels.

Value Assignment was performed on one instrument by one set of reagent for ASO analyte. ASO was measured 10 times (5 separate vials in duplicate) and the mean value of ASO was used to establish target concentration values at each level. The target ranges were calculated as ± 20% of the mean target value. The mean concentration values of each level were plotted (concentration value vs. assigned level) and a linear regression values were obtained. The five-point linear regression R^2 value is greater than 0.95 and the product demonstrates linearity.

Representative data from the ASO Linearity set is shown below for five lots:

Lot Numbers	100153	100154	100155	100156	100157
Levels	Level A	Level B	Level C	Level D	Level E
Mean Target Level (IU/mL)	51.4	448	836	1312	2083



c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: Values assigned to the Audit™ Micro CV™ ASO Linearity Set can be traced to ASO Reagent – 447620 and ASO Calibrator– 469975, Cal 5 obtained from Beckman and ASO Control– 472599 from Vigil Serology.

The base matrix for building the Low and High Pools is human serum. For the Low Pool (Level A), ASO is adjusted to be within 5% to 10% of the lowest limit of measurability for the ASO assay. For the High Pool (Level E), ASO is adjusted to be within 5% to 10% of the highest limit of measurability for the ASO assay.

An accelerated "Heat Stress Stability Prediction" stability study was conducted to predict shelf life. Five vials of each level were stressed at 37º C for 20 days to predict two-year stability when stored at 2 – 8º C.

Two pilot lots, Pilot 1, Lot 100153-100157 and Pilot 2, Lot 100158-100162, were produced and tested. For both pilots, ASO in the stress stability study results were within ± 15% of the Day Zero value. This gives the ASO Linearity Control two-year shelf life stability.

Accelerated stability studies are supported by an on-going real-time stability studies.

Open vial stability was also performed to determine the viability of the product during the course of normal use. Five vials of each level (A through E) were opened and exposed to the environment for 30 minutes then closed and repeated for a total of 3 cycles. Vials are then closed and stored for 24 hours at 2-8 º C and tested following the same manner as the above stated destructive testing. The percent loss determined in comparison to Day Zero values was < 15% and the product is considered stable.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

   a. Method comparison with predicate device:

   Not applicable

   b. Matrix comparison:

   Not Applicable

3. Clinical Studies:

   a. Clinical Sensitivity:

   Not Applicable

   b. Clinical specificity:

   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not Applicable

4. Clinical cut-off:

   Not Applicable

5. Expected values/Reference range:

   See section 1b above.

N. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.