1. PURPOSE

1.1. The purpose of this to establish and follow the standard acceptance criteria for difference of values obtained in Lot-to-Lot verification

2. SCOPE

2.1. This procedure is applicable all the personnel in the laboratory involved in testing

3. REFERENCES

3.1. Quality Manual
3.2. Kit Insert
3.3. Equipment Manual

4. RESPONSIBILITY

4.1. Quality Manager
4.2. Laboratory Director
4.3. Technical Staff

5. PROCEDURE

5.1. **Lot Verification**

5.1.1. A minimum of 2 patient samples or QC should be run on the old and new lot number
5.1.2. The new lot controls should be run in parallel with the old lot controls
5.1.3. The mean for the new control and standard deviation for the new lot of the controls should be approved by the Quality Manager/Laboratory Director coordinator before the new control is put into use
5.1.4. The Quality Manager / laboratory Director should review and sign off on the QC parallel testing data before the new control is put into operation
5.1.5. The values are recorded in a register and instrument generated print outs of Lot verification is stored in separate file
5.1.6. The values are recorded in a register and instrument generated print outs of Lot verification is stored in separate file
1.1.1. The Formula used to calculate the difference in percentage is Difference of value /High value X 100 = % of Deviation

1.2. **Chemistry Assays**

1.2.1. New lot numbers of chemistry reagents are run in parallel with the old lot to check the performance of the new reagent
1.2.2. A minimum of 2 patient samples are run on the old and new lot number
1.2.3. The QC and patient results should be reproducible between the two lots
1.2.4. The Formula used to calculate the difference in percentage is Difference of value /High value X 100 = % of Deviation
1.2.5. The values are recorded in a register and instrument generated print outs of kit lot verification is stored in separate file
1.2.6. The Quality Manager / Laboratory Director designated technologists are responsible for defining the acceptability limits for reagent parallel testing

1.2.7. The Lot acceptance criteria is established as below:

1.2.7.1. Acceptability limits are within +/- 1 SD / or within +/- 10 %

1.2.8. The Lot validation process includes the following data:

1.2.8.1. Lot numbers (old and new lot numbers) and expirations dates

1.2.8.2. Results obtained from the old and new lots

1.2.8.3. Criteria for acceptance and space to indicate if the results obtained on the new lots were acceptable

1.2.8.4. QC values on both runs (include QC lot numbers)

1.2.8.5. Space for the person completing the parallel testing to sign and date the form and a place for a reviewer to sign and enter the date

2. RECORDS

2.1. The following records are maintained in the laboratory for the period defined:

S. No	Record	Responsibility	Review Period	Retention Period
1.	Lot Verification Register	Incharge	1 Year	1 Year