- if applicable the statistical methods applied
- All persons involved in the test procedure can be identified by the accompanying **Testing Laboratory** test documents
- Name, title and signature of the authorized person issuing the test report
- Name, title and signature of the authorized person reviewing the test report
- All associated test raw data to be send to customer

4.8. Retained Samples

Both **Testing Laboratory** and **Company** shall be entitled to store retained samples after tests have been conducted. The number of retained samples and their place of storage shall be defined. Retained samples must be clearly identified as such.

A record must be kept of the samples and test specimens which are destroyed.

Samples and test specimens which are no longer needed shall not be handed over to third parties for other purposes. They must be sent back to **Company** or destroyed if decided by **Company**.

4.9. In-House-Method validation

The In-House-Method validation must be managed in a defined procedure. A validation protocol describing all activities to be performed must be established prior to each validation. It shall identify the performance parameters relevant for the method. The validation process must be documented appropriately and all raw data must be kept. From the validation studies a suitability test with acceptance criteria must be concluded in order to verify the actual suitability of the method and equipment. This test shall be applied each time when the method is performed.

After completion of validation a validation report must be issued which contains at minimum:

- The details of all experimental studies performed
- All experimental data
- Detail of all calculations, or appropriate references
- An evaluation of the results in relation to the defined acceptance criteria

It must be verified that a method maintain its validation status during the whole life-cycle.

4.10. Test equipment

All testing equipment must be adequate for the intended purpose, qualified, calibrated and maintained. The calibration of the testing equipment shall be traceable to national standards. Adequate records must be maintained for each instrument. The qualification of the instrument used must be prerequisite for method validation.