

Manual 057

6.1 Appendix 1 Examples of Atypical Results

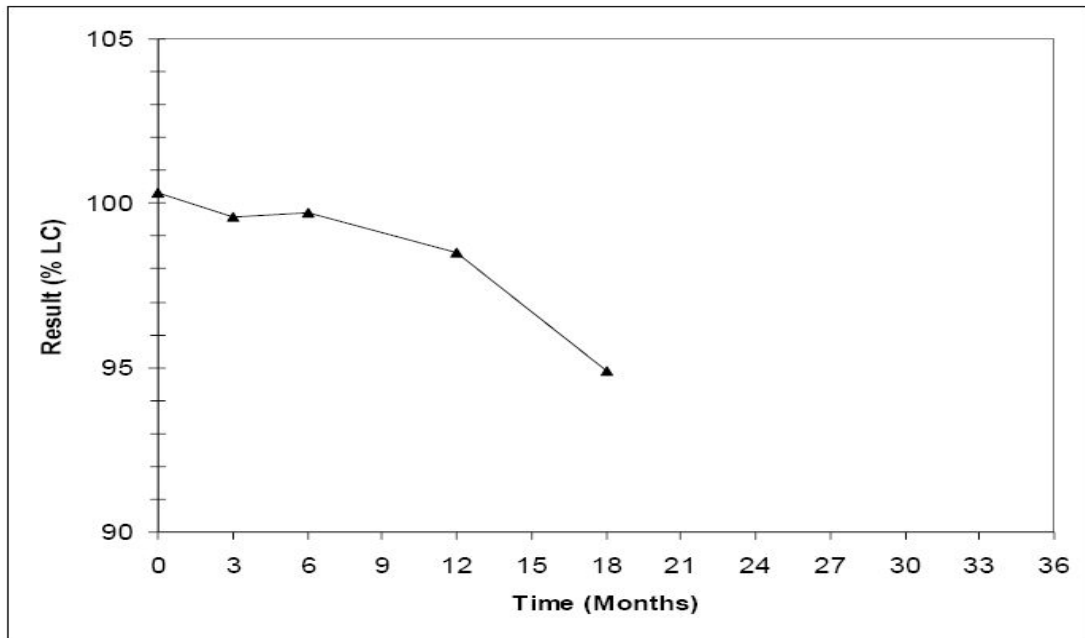


Figure 1: A possible single atypical result

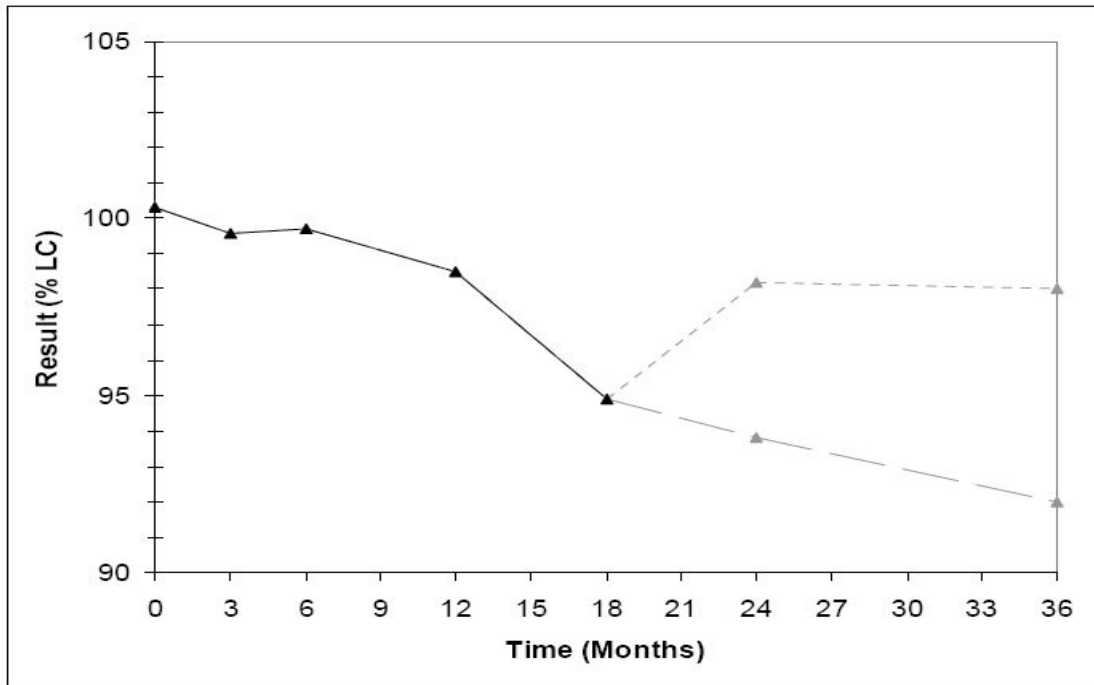
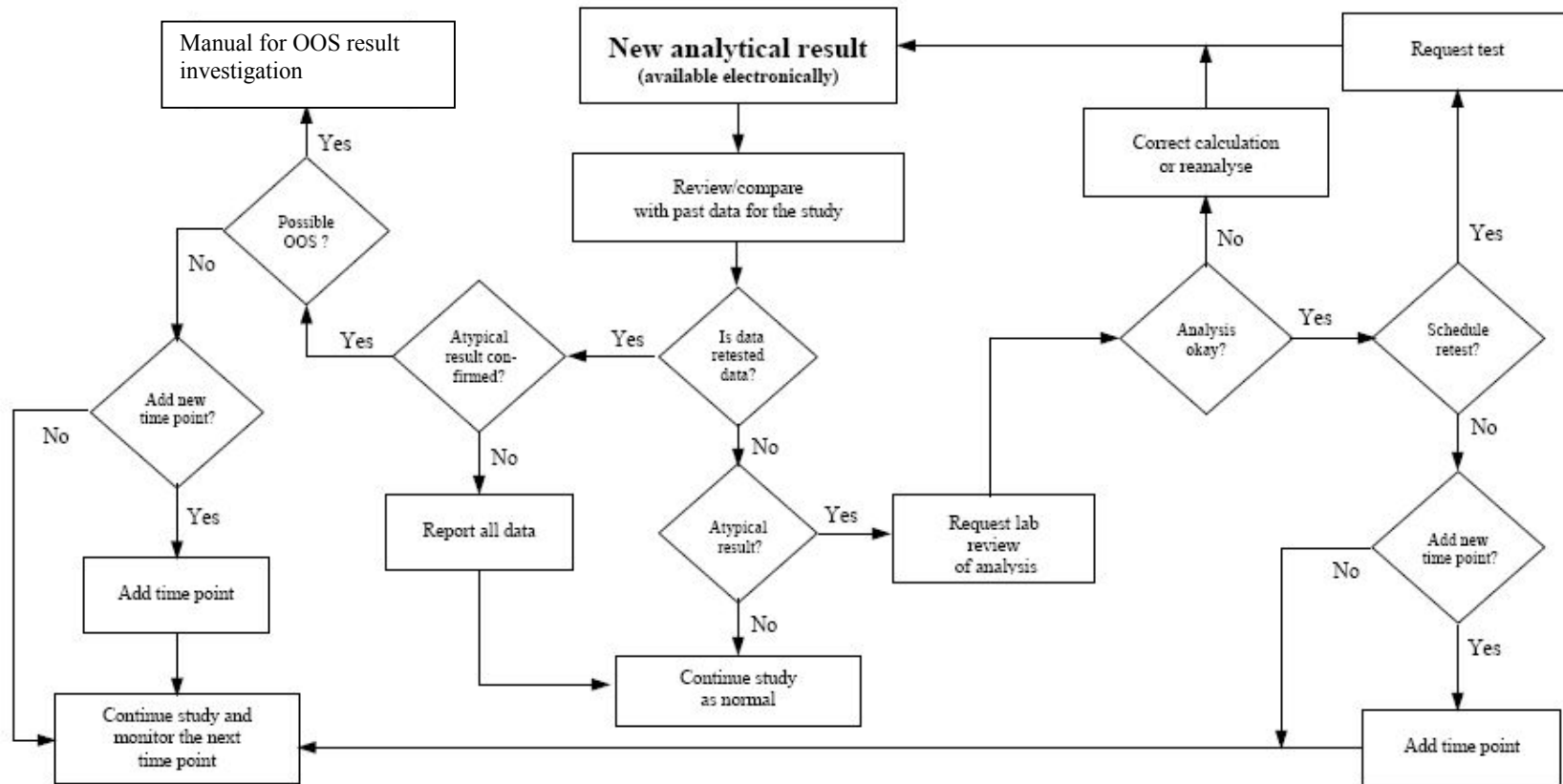


Figure 2: Two possible outcomes of subsequent results

6.2 Appendix 2 Atypical Result investigation



6.3 Appendix 3 Examples of Atypical and Adverse Trends

Figure 3 shows a study that appears to have a different trend compared to other studies, but as shown in figure 4, it might not appear “strange” without that comparison (no single atypical results within the study).

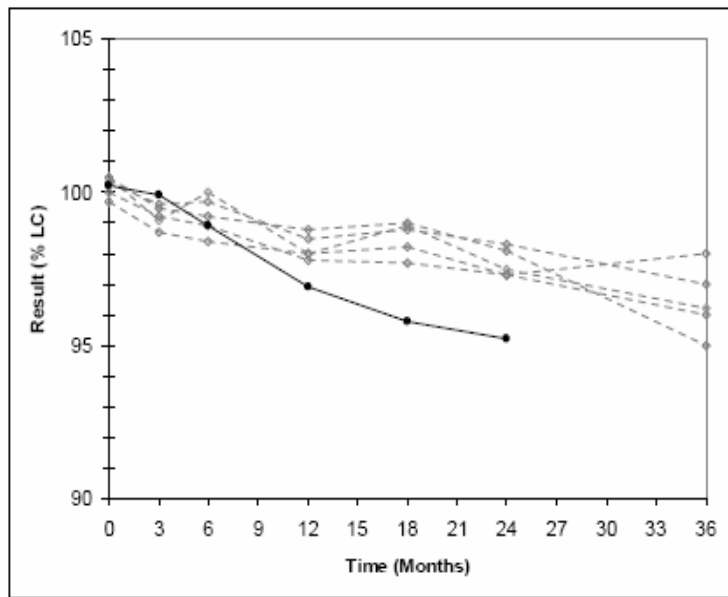


Figure 3: An atypical trend compared to other studies

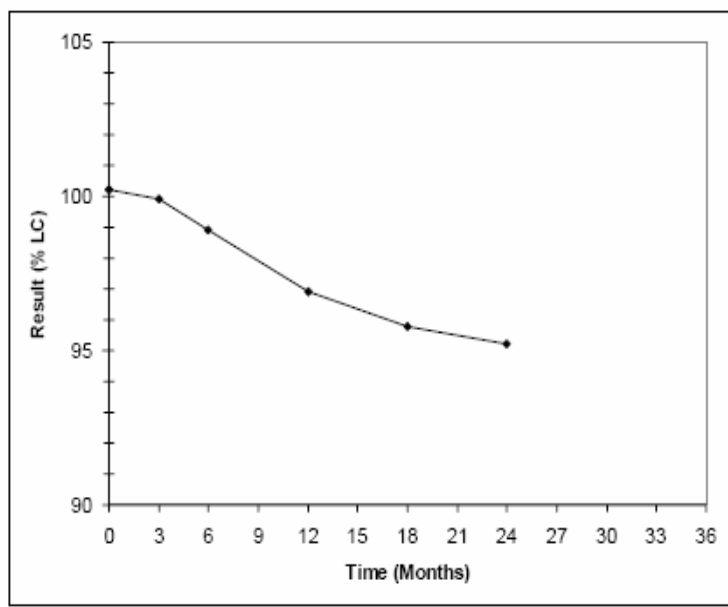


Figure 4: An atypical trend without comparison with other studies

Figure 5 shows a situation where a single atypical result within a study can form a trend (in comparison with previous results within the study) that is atypical in comparison with other studies. If this single result is close to the specification limit it may be considered to be an adverse trend.

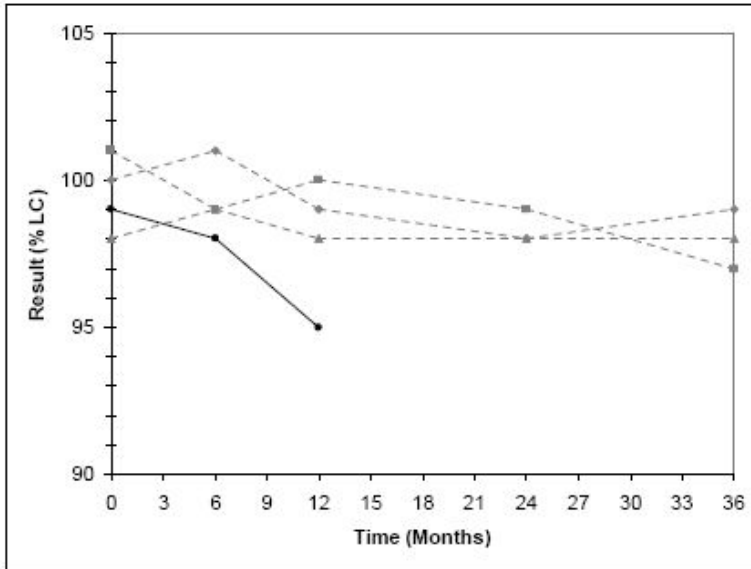


Figure 5: A single result within a study resulting in an atypical trend compared to other studies

The two consecutive atypical results and the atypical results occurring in different studies (mentioned in example 2 & 3) are shown in figure 6 & 7.

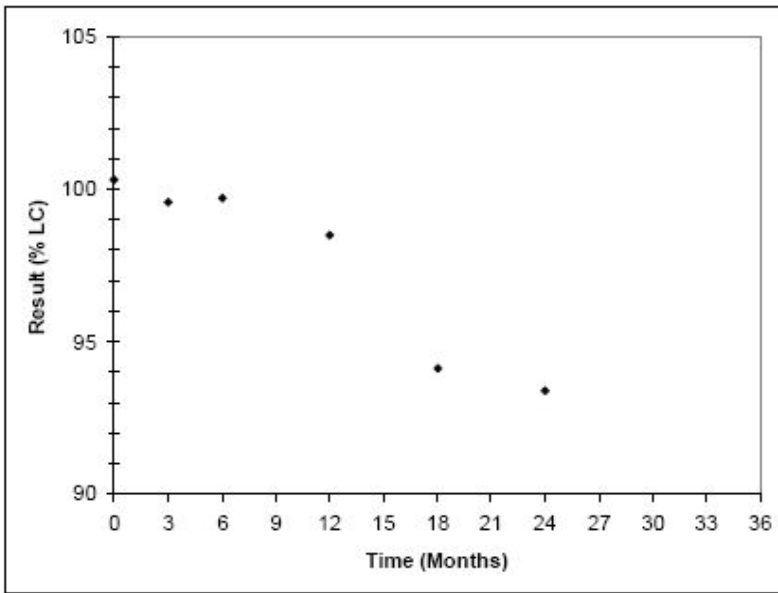


Figure 6: Two consecutive atypical results

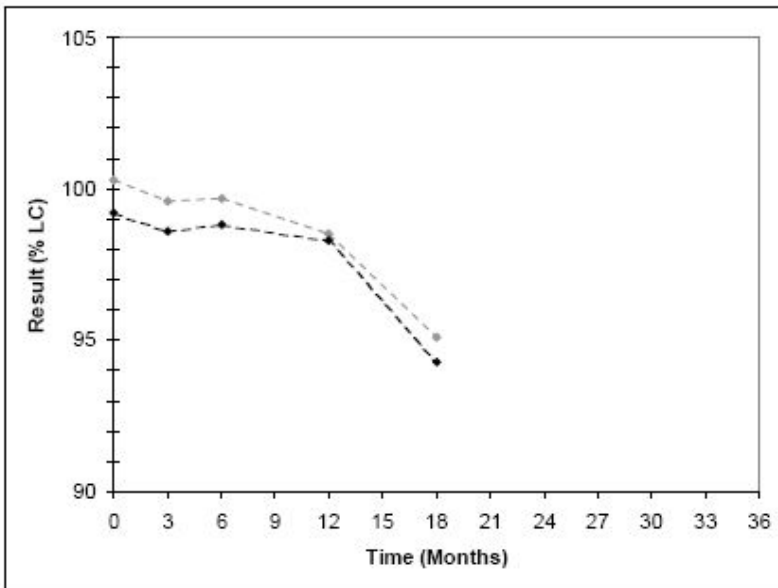


Figure 7: A single atypical results in two studies

A clearly atypical trend as shown in figure 8 might not result in an adverse trend, but since the trend is not expected, it could still be of interest for further investigation.

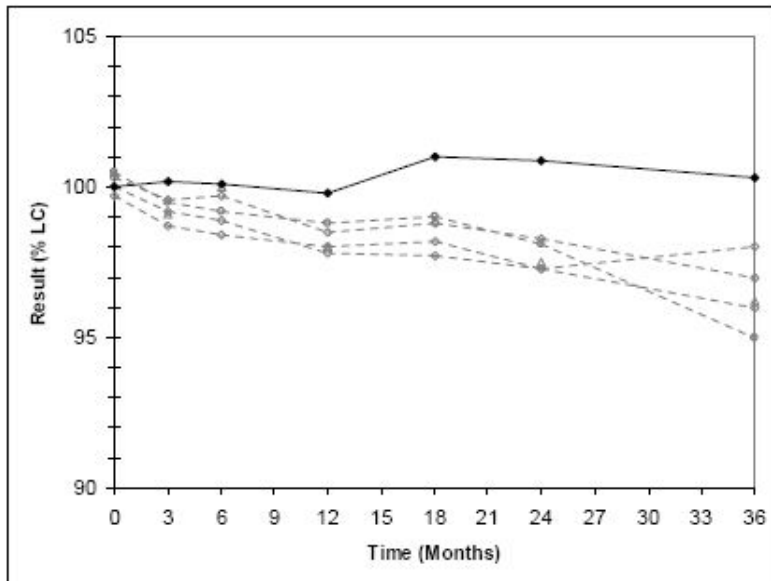


Figure 8: An atypical (but not adverse) trend

The opposite situation, not clearly atypical, but adverse trend is illustrated in figure 9. The trend is typical, but slightly worse. This is most likely to occur when the initial value for a parameter in a normal behaving stability study is near to its specification limit.

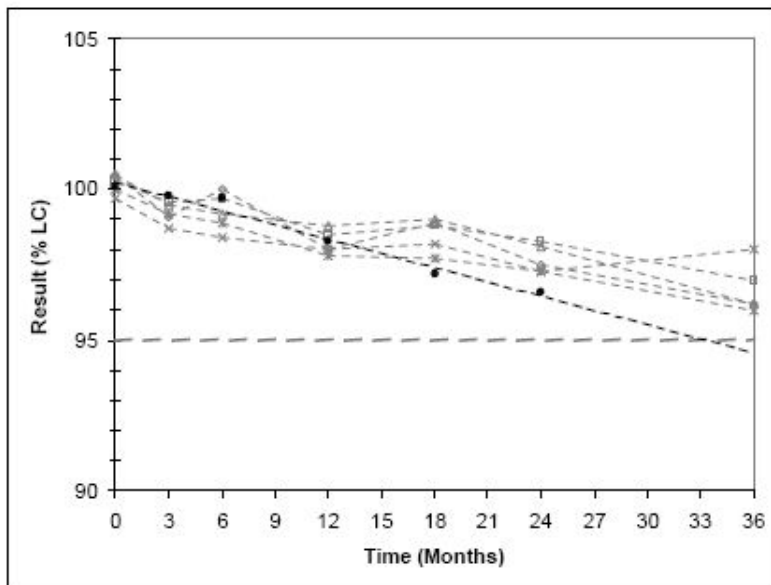


Figure 9: A not evident atypical result but possibly adverse trend

6.4 Appendix 4 Atypical Trend Investigation

