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## ROLE OF DELTA CHECK IN CLINICAL LABORATORY SERVICES

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### ABSTRACT

Delta check is a process during post-analytical phases to detect discrepancies of test results before reporting by comparing current patient values to the previous test result. It is one of the efforts in assuring the quality of laboratory test results. It has to be done although control of sampling, control of method, control of the instrument, control of reagents as well as control of data distribution has been done well. The difference between those two test results is compared to a delta check limit that is specific for the test parameter within a predefined time interval. A time interval is flexible, and usually, most hospital laboratories choose 24 or 48 hours. Delta check limits should be defined so that both acceptable and unacceptable changes could be detected. Delta check limits should be based upon the total expected variation on both biological, and analytical variation. Delta check limits can be expressed as the absolute or percent difference between two consecutive results. The delta check system is addressed to evaluate changes in patient condition as well as quality sample issues and patient misidentification.

**Key words:** Delta check, delta check limit, quality improvement, patient safety

### INTRODUCTION

Delta check is a process during post-analytical phases to detect discrepancies of test results before reporting by comparing current patient values to the previous test result. The use of it in clinical laboratory service is one effort to improve quality and patient safety.<sup>1,2</sup>

Lindberg introduced delta check in 1967 as a new concept related to emerging technology in laboratory informatics. Nosanchuk and Gottman who also considered Linberg approach introduced an operational system designed effectively to identify laboratory errors from a wide range of sources. Based upon accumulated results of each patient kept in a consecutive serial consecutive record (CUM), comparisons (Delta Checks) were made between previous results (database), and current results. In this system, validity was certified by checking specimen acquisition, quality control data, instrumentation, methodology, transcription, current, and previous clinical status of the patient. All of these things were done manually.<sup>3</sup>

Subsequently, Ladenson introduced a computer based system of quality control where patients were placed as their controls to detect laboratory error and called as delta check system. It was used to follow all the tests performed by the clinical chemistry laboratory of a 1,200-bed hospital. Evaluation during 22 months follow-up period

showed that this system was able to identify specimen misidentification that was a serious problem in the clinical chemistry laboratory. The system detected errors most frequent in the results for total thyroxin, total calcium, and total protein over nine-month period. Laboratory errors detected by the delta check system were not detected by other quality control methods available at that time.<sup>4</sup> Another study used computer-based real-time delta check system and was done to evaluate the capability of detection. During a month, 1,403 delta check messages were reviewed and 55 (3.9%) were detected that could not be explained based on the clinical condition of the patients. Twenty-three out of them represented true laboratory errors and were corrected. Specimens mislabeling and otherwise mishandling were found prior to wrong results available on medical records.<sup>5</sup> In principle, the delta check system currently has not been changed, but efforts have been made to incorporate it into the laboratory information system. The objective of this review is to discuss the role of delta check in laboratory services.<sup>5</sup>

### DISCUSSION

Laboratory errors may occur in laboratory service. Therefore, they have to be detected and appropriately managed to improve quality and patient safety. Laboratory examination is used to

follow up alteration of important clinical state. Changes in serial laboratory tests may result in discrepant results. The discrepancy of 2 consecutive laboratory test results may be either small or large. Plausibility analysis should be done whether the changes are acceptable or not. The cause of discrepant results can be from pre-analytical variation, analytical variation, and biological variation. The pre-analytical variation includes patient misidentification, specimen related issues, and post-collection, whereas both instrument and methods contribute to analytical variation. Rhythmic changes, lifespan, and treatment are factors that contribute to developing biological variation. These variations may occur in hematological tests, procedures of point care test, immunology, and molecular/genetics tests, multiple analyte delta checks.<sup>6</sup>

The delta check concept is applied to two consecutive values regardless of the time interval between them. Delta check values could be generated using two approaches. The first approach is derived from the differences between the consecutive collected values for an analyte in a group of patients, which are subsequently plotted in a histogram so that distribution data of delta difference can be established. Delta check may involve the absolute difference or percent change between consecutive numbers. The second approach in determining the delta relies on the best estimation of an appropriate delta of laboratory physician to yield a manageable number of flagged results for follow-up. A more refined means of using patient data for assessing statistically significant changes is through rate checks that involve dividing delta check value by the time interval between successive measurements.

Delta check method may be just based on a delta difference which is the difference between the current laboratory test result minus the previous laboratory test result.<sup>3,4,6</sup> It is also named absolute.<sup>5</sup> The method also can be based on delta percent change or percentage in which the current laboratory test result minus the previous lab test result X 100% divided by the earlier laboratory test result.<sup>7</sup> The result of the method is also expressed using rate difference that can be calculated from delta difference divided by delta time.<sup>5,7</sup> Delta check method may also be based on the rate percent change which is derived from delta percent change divided by delta time.<sup>7</sup> The delta check method may be integrated into the laboratory information system in the reporting test result but usually in the most straight forward way such as delta difference or delta

percent change.

After delta check value is determined then delta check limits are needed in order to detect laboratory errors. Delta check limits have to be determined properly, if it is set too low compared with biological variation and analytical variation, a lot of test results will exceed the delta check limit. Conversely, if the delta check limit is set too high it will give rise to many false negatives. Delta check limit can be derived either from biological variation and known as Reference Change Value (RCV) or from patient data. The following formula can calculate the RCV values as the delta check limit:

$$\text{RCV} = 1.414 \times \text{Z score} \times [\text{CV}_A^2 + \text{CV}_I^2]^{1/2}$$

$\text{CV}_A$  = analytical coefficient of variation  
 $\text{CV}_I$  = intra-individual biological coefficient of variation individual

Z score 95% CI = 1.96

Z score 99% CI = 2.58

Z score 99.9% CI = 3.29

Delta check limits are derived from the population distribution of delta percent change, and their 0.5<sup>th</sup>, 2.5<sup>th</sup>, 97.5<sup>th</sup>, and 99.5<sup>th</sup> percentiles were then used for delta check limits. If 95% central range is used the lower limit is 2.5<sup>th</sup> percentile, and the upper limit is 97.5<sup>th</sup> percentile. Whereas if ((% central range is used, the lower limit is 0.5<sup>th</sup> percentile and the upper limit is 99.5<sup>th</sup> percentile.<sup>8</sup>

A lot of false positives of delta check can be found, especially in those patients who are taken care of in the intensive care unit and it may lead to increased laboratory test requests or alterations in patient care. False-negative of delta checks may be due to specimen mislabeling, and it may cause delayed recognition of significant clinical alterations. Laboratory errors can be easier identified using correlation among delta checks.<sup>6,9</sup>

Delta checks should be applied to parameters that show the least short-term biological variation. For example in hematology, MCV and MCHC are incredibly stable in a patient over a short interval, such as 24 hours. The diurnal biological coefficient of variation of MCV is only 0.5%. Even in medical situations where other hematological parameters are changing rapidly, such as bleeding and, MCV. MCHC do not change significantly since the reticulocyte response does not begin for two to three days. MCHC has the added benefit of detecting instrument malfunction because it is calculated from hemoglobin, MCV, and RBC count.<sup>9</sup>



The index of individuality (II) is mainly used to evaluate the suitability of reference ranges based on the calculation for the normal population. If II is more than 1.4, then the reference range based on the normal population can be used to determine abnormal detection values for an individual. And if II is less than 0.6, the reference range, based on the normal population, has a limited capacity to determine whether the detection value for an individual is abnormal. This parameter is primarily suitable for observing disease progression or determining prognosis and, under such circumstances; the results of continuous patient follow-up may be more effective than using the reference range alone. Index of individuality can be calculated using the formula:<sup>9</sup>

### Index of individuality (II) = CVI /CVG

CVI = Intra-individual coefficient of variation

CVG = inter-individual coefficient of variation

Mislabeled or identification errors are one of the most common pre-analytic errors in laboratory services. The identification error range is from 2.6% to 58% interlaboratory.<sup>10</sup> Pre-analytical error totally is around 46%-68.2% which includes inappropriate test request, Order entry errors, misidentification of patient, inappropriate container, sample collection and inadequate transport, inadequate sample/anticoagulant volume ratio, insufficient sample volume, sorting and routing errors, and labeling errors.<sup>11</sup> According to the first goal of the International Patient Safety Goal, patient has to be identified correctly so that it is a key point in patient laboratory processing. Proper the patient identification relies on at least two unique identifiers and the sample has to be labeled in front of the patient.<sup>12</sup> All patients who are either conscious, or unconscious, or too young, or cognitively impaired, or does not speak the language of the phlebotomist, or semi-conscious, or comatose or sleeping, or an unidentified emergency patient has to be identified correctly.<sup>13</sup>

Mostly, delta checks analysis is conducted for quantitative data, but now it is also done for qualitative data such as blood groups. Makroo and Bhatia conducted a study on the use of delta check for blood groups as an effort to improve blood safety.<sup>12</sup> They retrieved the records of all transfusion related incidents reported in their institute. Errors identified as "Failed Delta checks" and their Root-Cause Analyses (RCA) were reviewed. They found that 38 out of 17,034 errors related to blood

transfusion were due to blood grouping. Seventeen blood group errors were detected caused by failed delta checks, where the results of two individually drawn grouping samples yielded different blood group results. The root-cause analysis showed that all of these errors occurred in the pre-analytical phase. Mislabeled gave rise to wrong blood in a tube was the most frequent cause, accounting for eleven of these errors, while problems with correct patient identification accounted for five failed delta checks.<sup>14</sup>

### CONCLUSION

Delta check is done in post-analytical phases to detect discrepancies of test results before to reporting test result by comparing current patient values to the previous test result. Subsequently, the delta check value is compared with delta check limit to evaluate whether the changes have to be reviewed or not. The review will define whether the difference is acceptable or unacceptable. The unacceptable change will be scrutinized further to define laboratory error. Not all of the laboratory test parameters are subject of delta check but only those parameters which have an index of individuality more than 1.4. Initially, delta check is applied for interval or ratio data, but recently it is also used for nominal data such as blood grouping in blood transfusions. Delta check is one of the quality assurance efforts to improve the quality of service and patient safety.

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