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Effective and Practical Complete Blood Count Delta Check Method and Criteria for the Quality Control of Automated Hematology Analyzers

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Background: Delta checks increase patient safety by identifying automated hematology analyzer errors. International standards and guidelines for the complete blood count (CBC) delta check method have not been established. We established an effective, practical CBC delta check method and criteria.

Methods: We assessed five delta check methods for nine CBC items (Hb, mean corpuscular volume, platelet count, white blood cell [WBC] count, and five-part WBC differential counts) using 219,804 blood samples from outpatients and inpatients collected over nine months. We adopted the best method and criteria and evaluated them using 42,652 CBC samples collected over two weeks with a new workflow algorithm for identifying test errors and corrections for Hb and platelet count.

Results: The median delta check time interval was 1 and 21 days for inpatients and outpatients (range, 1–20 and 1–222 days), respectively. We used delta values at 99.5% as delta check criteria; the criteria varied among the five methods and between outpatients and inpatients. The delta percent change (DPC)/reference range (RR) rate performed best as the delta check for CBC items. Using the new DPC/RR rate method, 1.7% of total test results exceeded the delta check criteria; the retesting and resampling rates were 0.5% and 0.001%, respectively.

Conclusions: We developed an effective, practical delta check method, including RRs and delta check time intervals, and delta check criteria for nine CBC items. The criteria differ between outpatients and inpatients. Using the new workflow algorithm, we can identify the causes of criterion exceedance and report correct test results.

Key Words: Blood cell counts, Delta check method, Delta check criteria, Quality control, Automated hematology analyzer, Automation

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INTRODUCTION

Delta checks are used to compare current and previous test results and to estimate the probability of significant changes. When the difference between current and previous results exceeds predefined criteria, the cause of the error is identified by retesting all samples for QC. The difference exceeding the delta check limits provides an opportunity to determine the cause of the error and retest for correcting the error to identify sample mix-ups. A delta check can be an important component of autoverification procedures to improve laboratory efficiency [1-3]. Mild (high) delta check limits decrease the retesting rate and turnaround

time (TAT) but can miss errors, leading to decreased sensitivity of the laboratory results. Strict (low) delta check limits increase labor intensity.

There are numerous reports on delta check methods and limits for chemistry laboratory results. Most studies on delta checks for chemistry items attempted to establish delta check methods and limits (criteria) based on empirically established methods and reported limitations to the application of the reference range (RR)-based delta check method [4-13]. Some recent studies have used machine learning for delta check [14, 15]; however, few studies on hematologic tests have been published. Fu, *et al.* [16] simplified the delta check limitation formulae for data review and reported a new delta check model for automated complete blood counting that improved data validation. Miller, *et al.* [17] suggested a new mean corpuscular volume (MCV)-based delta check method and limits (>3.0 fL) for hematology laboratories. In Korea, Park, *et al.* [18] in 1989, Yang, *et al.* [19] in 1991, and Koo, *et al.* [20] in 2012 reported their experiences with the delta check method and empirically established delta check criteria for automated hematology analyzers. Although these review articles suggested the need for studies on the delta check method for hematology, no such studies have been published to date. Many laboratories have empirically established delta check methods and limits for hematologic tests. Therefore, an effective delta check method and criteria for hematologic tests are needed.

We aimed to establish an effective and practical complete blood count (CBC) delta check method and criteria using statistics for the QC of automated hematology analyzers. In addition, we suggest a practical process with a new workflow algorithm for improving validation in the hematology laboratory.

MATERIALS AND METHODS

This study was conducted in accordance with the Declaration of Helsinki (2013 revision) and was approved by the Institutional Review Board of Asan Medical Center, Seoul, Korea (#2019-0803).

Data collection

All blood samples for CBC tests were collected using K2EDTA tubes (Becton Dickinson and Company, Franklin Lakes, NJ, USA). Samples were collected from outpatients and inpatients, including patients in the emergency department of Asan Medical Center (a 2,715-bed tertiary hospital with 49 clinical departments or divisions, specialized centers, and departmental specialist clinics). In total, 219,804 samples were obtained from 151,120 inpatients and 68,684 outpatients between May 2019 and January 2020. Patients were included regardless of the department, their age, or medical status. Data on nine CBC items were collected in pairs of previous and current results. The nine CBC items were white blood cell (WBC) count, WBC differential counts (neutrophil %, lymphocyte %, monocyte %, eosinophil %, and basophil %), Hb, MCV, and platelet count. All EDTA-anticoagulated blood samples were analyzed using a Sysmex XN-20 automated hematology analyzer (Sysmex Co., Kobe, Japan). All data, including delta check time intervals and clinical features, were obtained from the laboratory information system and electronic medical records.

Delta check using five methods

The five delta check methods used in this study were as follows:

(1) Absolute delta difference (ADD) = |current result–previous result|
(2) Delta percent change (DPC) (%) = |current result–previous result|/previous result × 100%
(3) DPC rate (%/day) = |current result–previous result|/previous result/delta interval × 100%
(4) DPC/RR (%) = |current result–previous result|/previous result/RR × 100%
(5) DPC/RR rate (%/day) = |current result–previous result|/previous result/RR/delta interval × 100%

The DPC and DPC/RR rates included the RRs of the laboratory items. The RRs used in this study are shown in Supplemental Data Table S1. We used the best-performing delta check method and criteria for the nine CBC items.

Evaluation of the new delta check method

For the evaluation of the new delta check method and criteria, we used paired CBC data from 42,652 samples (294,588 tests) collected between March 25 and April 7, 2020. Tests and samples yielding results exceeding the delta check criteria were counted. The samples yielding results exceeding the criteria were evaluated according to a new workflow algorithm to identify errors and corrections (Fig. 1) and the causes of the errors for Hb and platelet count [21-23]; for the other CBC items, manual review (peripheral blood smear and stain) and electric medical records were used.

Statistical analysis

A distribution of the delta check values for the CBC items (Hb, MCV, platelet count, WBC, and five-part WBC differential counts)

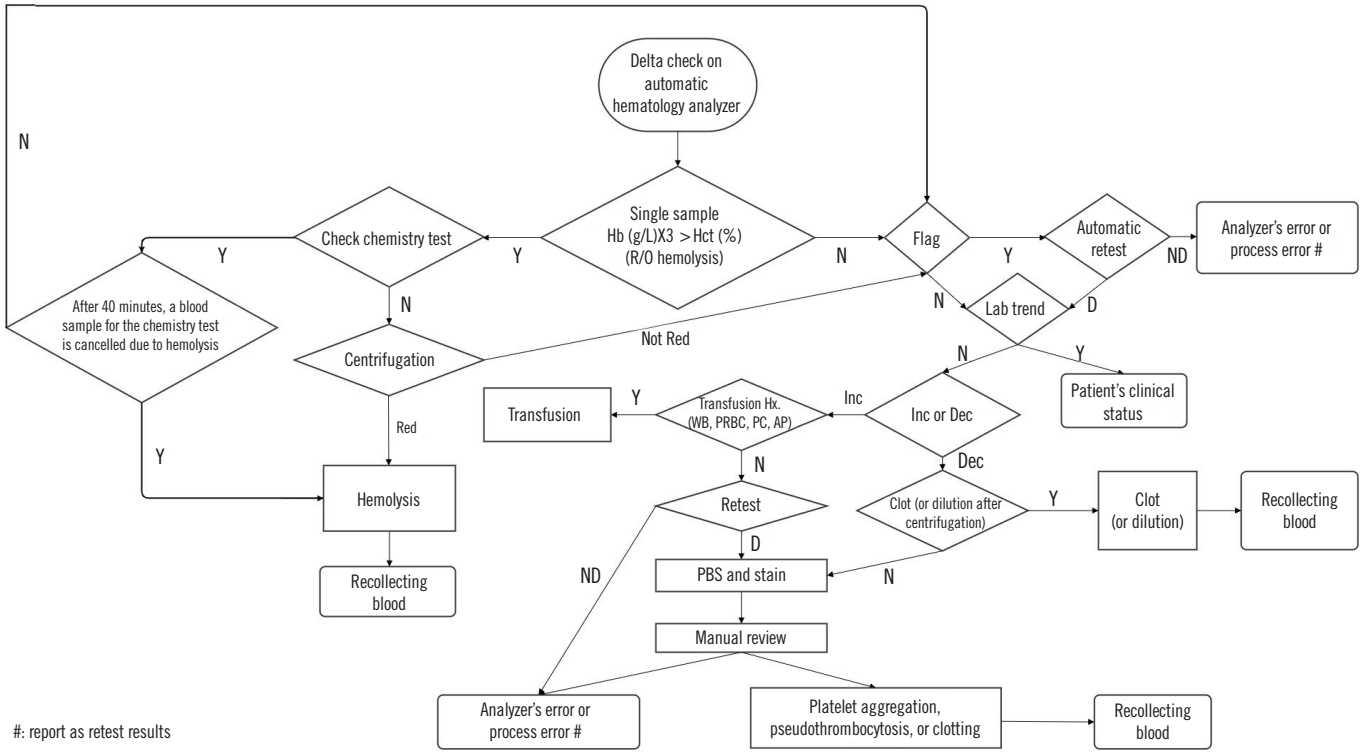

Fig. 1. Workflow algorithm used to investigate samples exceeding the delta check criteria for Hb and platelet count.
Abbreviations: Y, yes; N, no; D, sample included in the delta check; ND, sample not included in the delta check; Inc, increase; Dec, decrease; Hct, hematocrit; WB, whole blood; PRBC, packed red blood cell; PC, platelet concentrate; AP, apheresis platelet; PBS, peripheral blood smear; Hx., history.

Table 1. Distribution of delta check time intervals and delta check values for Hb according to the five delta check methods in outpatients (N=151,120) and inpatients (N=68,684)

Distribution (%)	Delta check time interval (day)		Absolute delta difference (g/dL)		DPC (%)		DPC rate (%/day)		DPC/RR (%)		DPC/RR rate (%/day)	
	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients
99.5	84	20	3.1	2.8	30.1	23.1	4.1	19.6	7.5	5.8	1.0	4.9
97.5	69	8	2.0	1.9	17.7	16.0	1.8	14.0	4.4	4.0	0.5	3.5
50.0	21	1	0.4	0.4	3.7	4.0	0.2	2.8	0.9	1.0	0.0	0.7
2.5	2	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.5	1	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Abbreviations: DPC, delta percent change; RR, reference range.

was obtained using SPSS version 26.0 for Windows (IBM Corp., Armonk, NY, USA) (Table 1). Microsoft Excel 2016 (Microsoft, Redmond, WA, USA) was used to calculate the delta check criteria (Table 2) and to determine the percentage of tests that exceeded the delta check criteria and causes for Hb and platelet counts exceeding the delta check criteria (Table 4 and Supplemental Data Table S2).

RESULTS

Distributions of delta check time intervals and delta check values according to the five delta check methods

Table 1 presents the distributions of delta check time intervals and delta check values for Hb, as an example of the nine CBC items, according to the five delta check methods and patient type (outpatient or inpatient). The median delta check time interval for Hb was one day (range, 1–20) for inpatients, including

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Table 2. Frequencies of values ≥99.5% in the distribution of delta check values for the nine CBC items tested by the five delta check methods in outpatients (N=151,120) and inpatients (N=68,684)

CBC item	Absolute delta difference (%)		DPC (%)		DPC rate (%)		DPC/RR (%)		DPC/RR rate (%)	
	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients
Hb (g/L)	0.9	0.8	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.0
MCV (fL)	1.0	1.0	1.0	1.1	0.9	1.1	1.1	0.9	1.0	1.0
Platelets (10^9/L)	1.0	1.0	1.0	1.0	1.1	1.0	1.1	1.1	1.3	1.0
WBCs (10^9/L)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.9	1.0
Neutrophils (%)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1
Lymphocytes (%)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.0
Monocytes (%)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.9	1.0
Eosinophils (%)	0.9	0.9	1.0	1.1	1.1	1.0	0.9	1.0	0.9	1.0
Basophils (%)	1.1	0.6	0.7	0.9	1.1	1.2	0.8	1.0	1.1	1.2

Abbreviations: CBC, complete blood count; MCV, mean corpuscular volume; WBCs, white blood cells; DPC, delta percent change; RR, reference range.

Table 3. Delta check criteria based on delta check values ≥99.5% in the distribution with a frequency of 0.9%–1.1% for the nine CBC items tested by the five delta check methods

CBC item	Absolute delta difference		DPC (%)		DPC rate (%/day)		DPC/RR (%)		DPC/RR rate (%/day)*	
	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients
Hb (g/L)	31.0	28.0	30.1	23.1	4.1	19.6	7.5	5.8	**1.0**	**4.9**
MCV (fL)	8.8	5.9	9.5	6.1	1.2	5.3	0.5	0.3	**0.1**	**0.3**
Platelets (10^9/L)	288.0	172.0	186.8	82.8	20.4	53.0	0.06	0.03	**0.01**	**0.02**
WBCs (10^9/L)	12.2	12.8	285.7	204.9	57.9	175.0	47.6	34.2	**9.7**	**29.2**
Neutrophils (%)	49.8	43.5	235.0	126.6	64.6	100.4	9.4	5.1	**2.6**	**4.0**
Lymphocytes (%)	40.1	35.2	264.0	316.7	44.4	236.7	11.0	13.2	**1.9**	**9.9**
Monocytes (%)	19.8	14.0	673.3	492.7	80.4	349.3	96.7	70.8	**11.5**	**49.9**
Eosinophils (%)	11.6	9.5	1,266.7	1,600.0	100.0	1,045.0	216.7	266.7	**16.7**	**175.0**
Basophils (%)	1.6	1.2	500.0	461.4	75.0	400.0	250.0	230.2	**37.5**	**200.0**

*The best delta check criteria for each CBC item in bold font.
Abbreviations: CBC, complete blood count; MCV, mean corpuscular volume; WBCs, white blood cells; DPC, delta percent change; RR, reference range.

emergency department patients, and 21 days (1–222) for outpatients. For all nine CBC items, the distribution of delta check values varied among the five methods and between outpatients and inpatients.

Frequencies according to the distribution of delta check values for the nine CBC items and the five delta check methods

The frequency of delta check values exceeding 99.5% in the delta data distribution was 0.9%–1.1% for the nine CBC items, regardless of the method and patient type. For basophil %, the frequency of delta check values exceeding 99.5% was 0.6%–1.2% (Table 2). As test error frequencies reportedly are approximately 1%, it is reasonable to select the delta check values ≥99.5% in the distribution with frequencies of 0.9%–1.1% as the delta check criteria (limits) [24-26]. Therefore, we adopted the delta check values at 99.5% in the distributions as the delta check criteria.

Delta check criteria for the nine CBC items and five delta check methods

The delta check criteria for the nine CBC items varied among the five methods and between outpatients and inpatients. For all nine CBC items, the delta check method based on the DPC/RR rate, which reflects biological variation and the delta check time interval, performed best and was therefore adopted as the

Table 4. Numbers of tests and samples yielding results that exceed the new delta check criteria for the nine CBC items using the new delta check method (based on the DPC/RR rate)

CBC item	N (%)
Hb (g/L)	976 (19.5)
MCV (fL)	327 (6.5)
Platelets (10^9/L)	804 (16.0)
WBCs (10^9/L)	295 (5.9)
Neutrophils (%)	199 (4.0)
Lymphocytes (%)	198 (4.0)
Monocytes (%)	147 (2.9)
Eosinophils (%)	1,163 (23.2)
Basophils (%)	899 (18.0)
Total	5,008 (100.0)

Abbreviations: CBC, complete blood count; MCV, mean corpuscular volume; WBCs, white blood cells.

new delta check method [4-11]. The delta check criteria for each CBC item are provided in the two rightmost columns (in bold font) of Table 3.

Analysis of tests and samples producing results exceeding the new delta check criteria for the nine CBC items using the new delta check method

The newly adopted DPC/RR rate-based delta check method was evaluated using 42,652 samples collected from outpatients and inpatients over a two-week period and a workflow algorithm for Hb and platelet count (Fig. 1); for the other CBC items, we used manual review (peripheral blood smear and stain) and electric medical records. Among the 294,588 tests, 5,008 test results (1.7%) exceeded the delta check criteria (Table 4). There were 1,318 retests (0.5% among 294,588 tests) and four resamplings (0.01% among the total of 42,652 samples). The most common cause for delta check criterion exceedance for Hb and platelet count was transfusion (60.1%), followed by preanalytical errors (6.3%) (improper or inadequate samples, diluted samples, and misidentification), operation (3.6%), disease progression (2.1%), blood clots (0.2%), *in vitro* hemolysis (0.1%) during sample collection, and platelet aggregation (0.1%) (Supplemental Data Table S2).

DISCUSSION

In Korea, several laboratories have empirically established delta check methods and limits to decrease the TAT and identify errors [18, 20]. Koo, *et al.* [20] reported that the delta check reduced unnecessary smear slides, rechecking, resampling, retesting, and telephone inquiries and concentrated workloads in specific times of the day. However, whether empirically established delta check methods and limits are adequate and effective for QC remained unknown.

For outpatients, the delta check time interval can range from one day to several years. If the time interval between the previous test and the follow-up test is long, the error may reflect an altered patient status rather than a real error, even when the sample has a delta check flag. Previous studies focusing on delta check time intervals in delta check methods have suggested that methods based on the DPC or DPC/RR rate (%/day) are better than those based on ADD, DPC (%), or DPC/RR [10, 11].

The RR is another important factor in the delta check method. Park, *et al.* [6] suggested a new delta check method based on the ratio of the delta difference to the width of the RR (DD/RR), which yielded more feasible and intuitive selection criteria and well explained changes in the results as it reflects biological variation in both the test items and clinical patient features. In this regard, the DPC/RR and DPC/RR rate delta check methods, which include RRs, are better than those based on the ADD, DPC, or DPC rate.

Considering patients' disease progression or recovery over time and biological variation, inclusion of the delta time intervals and RRs would be ideal. Therefore, both delta check time intervals and RRs should be included when establishing a delta check method and criteria. Therefore, we adopted a new delta check method based on the DPC/RR rate and established criteria to efficiently identify errors in CBC test results and reduce labor intensity.

The error frequency in laboratory systems is approximately 1% [24-26]. In this study, delta check criteria were obtained at 99.5% in the distribution of delta check values (absolute delta differences) with a frequency of 0.9%–1.1%. The delta check criteria differed between inpatients and outpatients for all nine CBC items. This is likely due to factors affecting the delta check calculation, including the inclusion of delta check time intervals, patients' clinical states, and phlebotomists' technical skills (e.g., adequate sampling and prompt transfer to the laboratory by experienced phlebotomists vs. potential inadequate sampling and delayed transfer to the laboratory by inexperienced nurses or doctors). Therefore, delta check criteria should be separately established for outpatients and inpatients.

Koo, *et al.* [20] demonstrated that the use of an empirically established delta check method reduced the TAT, decreased retesting and resampling rates, and increased automated report-

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ing rates. In this study, the retesting rate (0.5%) with the newly adopted delta check method (based on the DPC/RR rate) was lower than that (3.2%) with a previous delta check method (DPC% ≥50% for WBCs, platelets, neutrophil %, and lymphocyte %; ≥20% for Hb and MCV; and ≥160% for monocyte %, eosinophil %, and basophil %) empirically established in our laboratory. The TAT of the newly adopted method (mean, 32 minutes; range, 1–51 minutes) did not significantly differ from that of the previous method (mean, 32 minutes; range, 1–92 minutes). The maximum TAT of the newly adopted method was lower than that of the previous method. Therefore, if the evaluation duration would have been longer, a reduced TAT may have been observed.

The delta check method is aimed at determining sample misidentifications in laboratory QC programs. However, according to Schifman, *et al.* [10], transfusion and the patients' physical condition and treatment are common causes of delta check criterion exceedance. In a study by He, *et al.* [27], the most common causes of delta check alerts were changes in the patient's physiological status according to treatment and follow-up and interference from hemolysis, lipemia, or icterus. Therefore, a delta check can help identify disease progression based on patient status.

The delta check flag is a critical automated QC tool and is useful to quickly determine the causes of automated analyzer errors through workflow automation, including the detection of hemolysis, transfusion, platelet aggregation, and blood clotting, which are readily flagged by automated analyzers. Workflow automation can be established based on previous studies and laboratory experience [21-23].

Our study has some limitations. Comparisons between the existing and new delta check methods are required. In addition, workflow algorithms for CBC items other than Hb and platelet count remain to be established for the new delta check method.

In conclusion, using EDTA blood samples from outpatients and inpatients, we developed an effective and practical delta check method based on the DPC/RR rate, which includes RRs and delta check time intervals, and delta check criteria for nine CBC items. Delta check criteria have to be established separately for outpatients and inpatients. Using a new workflow algorithm for Hb and platelet count for identifying test errors and corrections, we were able to identify causes of delta check criterion exceedance and report correct test results.

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AUTHOR CONTRIBUTIONS

Park CJ conceived the initial study concept, designed the study, analyzed the data, and reviewed and edited the manuscript. Kim MS designed the study, analyzed the data, and wrote the original draft. Namgoong S and Kim SI performed the tests and analyzed the data. Cho YU and Jang S reviewed the manuscript. All authors reviewed and approved the final version of the manuscript.

CONFLICTS OF INTEREST

None.

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