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Keywords:	accuracy, precision, complete blood count, method comparison, total error observed

Analytical validation of the Mindray BC-75R Vet hematology analyzer and comparison with the Siemens Advia 2120i for application in dogs and cats

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Running head: Comparative validation of Mindray BC-75R Vet

Abstract. The BC-75R Vet (Mindray Animal Medical) is an innovative multi-species hematology analyzer that uses electrical impedance and SF-Cube technology (combining laser scatter, fluorescence, and 3-dimensional analysis) for CBC and reticulocyte analysis. We evaluated its analytical performance and compared it with the Advia 2120i (Siemens), a widely used analyzer in veterinary clinical pathology. CBCs were performed on EDTA-anticoagulated blood samples from 411 dogs and 225 cats submitted for routine testing. Analytical precision, linearity, carryover, and total observed error (TE_{obs}) were assessed according to ASVCP guidelines. We used a 2120i as the reference method and manual differential counts for WBC evaluation. RIs were calculated from 131 healthy dogs and 53 cats. The BC-75R Vet fulfilled the ASVCP requirements for repeatability (CVs <5% for most variables) and linearity ($r > 0.97$), with negligible carryover. TE_{obs} values were within ASVCP allowable error limits, except for WBC types in QC material, which remained acceptable for in-clinic use. Agreement with the 2120i was acceptable for most RBC-related variables; however, systematic and proportional errors were found for mean corpuscular hemoglobin concentration (MCHC) in both species, and a systematic error for mean corpuscular volume (MCV) was found in dogs. Agreement for WBC and platelet counts was generally good, although discrepancies were noted for monocyte and mean platelet volume in both species. These differences likely reflect methodologic differences and known challenges in feline hematology. Despite these limitations, the BC-75R Vet met ASVCP standards and appears suitable for routine testing in dogs and cats. Manual smear review remains essential in selected cases.

Keywords: accuracy; complete blood count; method comparison; precision; total observed error.

In veterinary medicine, CBCs are performed daily using automated hematology systems for both diagnostic and monitoring purposes, as well as in research settings. Regardless of the underlying reasons for these analyses, the broad range of species potentially investigated necessitates a species-specific validation of hematology analyzers given species differences in blood cells.¹⁷

According to the American Society for Veterinary Clinical Pathology (ASVCP) guidelines, validating new analyzers and evaluating their analytical performance are mandatory for assessing quality in veterinary clinical pathology and confirming their suitability in the species of interest.¹ From a hematologic perspective, validation—defined as the process used to determine whether the amount of error is acceptable for the intended use of an instrument or method—includes not only the evaluation of analytical imprecision and bias but also carryover, specific total allowable error, and confirmation or de novo establishment of RIs.^{1,20} *Systematic bias* describes a constant deviation between 2 analytical methods across the measurement range, meaning that 1 method persistently produces higher or lower values than the other. When the discrepancy between 2 methods increases or decreases in relation to the magnitude of the measurement, it is referred to as a *proportional bias*.¹ The verification of a new method involves confirming a laboratory's reliability and accuracy in executing a previously validated method; thus, in veterinary settings, it is essential to integrate both validation and verification to guarantee optimal performance of an instrument on animal specimens and to fulfil the minimum analytical requirements.¹

The range of hematology analyzers evaluated in the veterinary field is extensive, including in-house devices and point-of-care hematology analyzers; various technologies have primarily been explored in dogs and cats, such as laser-, impedance-, optical fluorescence-, and flow cytometry-based methods.^{3,12,14,21,22,28,30,31} However, the models 120 and 2120 (Advia;

Siemens) not only are among the most commonly used hematology analyzers in veterinary laboratories, but also have been the main choice in validation studies of new hematology analyzers. Additionally, these multi-species analyzers have been validated for use with various species, including dogs and cats.^{3,4,12,31}

The BC-75R Vet (Mindray Animal Medical) is an innovative, multi-species hematology analyzer. It combines electrical impedance with SF-Cube cell analysis technology (laser scattering, fluorescence, and 3-dimensional analysis). This system differentiates WBCs into 5 populations and measures reticulocytes, platelets (PLTs), and nucleated RBCs (NRBCs) in various veterinary species. Like any new instrument, independent validation is essential before incorporating it into routine workflows. To our knowledge, no data on the validation of the BC-75R Vet have been published that compare this analyzer with other systems for dogs and cats. We did not find publications when searching Google, PubMed, and Scopus, and combining the terms “Mindray BC-75R Vet”, “dog”, and “cat”.

We had 2 main objectives: 1) to validate and evaluate the analytical performance of the BC-75R Vet; 2) to compare this analyzer with a 2120i. We conducted our study in accordance with ASVCP recommendations, including the establishment of RIs for dogs and cats.

Materials and methods

Study design

We designed our study prospectively to obtain the analytical validation of the analyzer in dogs and cats, including the evaluation of precision, linearity, carryover, the method comparison with another hematology system used as the gold standard, and the calculation of RIs in healthy animals. We included fresh K₃EDTA-anticoagulated blood samples collected with evacuated blood tubes (Monovette; Sarstedt) from dogs and cats, originally submitted to the Veterinary

University Hospital (VUH)–Clinical Pathology Service (University of Bologna, Bologna, Italy) for routine clinical purposes between October 2023 and February 2025. Samples for CBC were collected by attending clinicians for clinical reasons, and only surplus material was used for our study. Samples with an inappropriate blood-to-anticoagulant ratio, marked lipemia, icterus, hemolysis, or the presence of clots upon visual inspection were excluded. Analyses were completed within 1 h for the 2 analyzers and within 3 h from sampling. Blood smears were prepared for all samples and stained with May–Grünwald–Giemsa (Sigma-Aldrich). Our study was approved by the local Scientific Ethical Committee.

BC-75R Vet and 2120i technical features

The BC-75R Vet veterinary hematology analyzer is based on the electrical impedance method and SF-Cube cell 3D analysis technology (with “S” indicating scatter and “F” fluorescence; **Table 1**).¹⁹ We operated the instrument with its dedicated software (v. 01.05.00.11336, 2021–2023; Mindray Animal Medical). A complete analysis (CBC and reticulocyte count) requires 70 μ L of whole blood or 48 μ L of capillary blood. Sampling mode can be automatic or manual, and we used both options in our study.

The electrical impedance method is used to analyze RBC variables and perform PLT counts (PLT count-impedance; **PLT-I**). In this method, diluted blood cells pass through an aperture under constant negative pressure generated by a pair of electrodes. As each cell traverses the aperture, it produces a transient change in resistance, generating an electrical pulse. The number of pulses indicates cell count; the amplitude of the pulse corresponds to cell volume. Hemoglobin (Hb) concentration is measured using a cyanide-free colorimetric method, with a reagent formulated to lyse RBCs, release Hb, and transform Hb into methemoglobin.

The SF-Cube cell 3D analysis technology enables 3-dimensional analysis by combining laser light scatter at 2 angles with fluorescence signals (low-angle scatter for cell size, high-angle scatter for intracellular granularity). This process is used to perform total and differential WBC counts, quantify NRBCs and reticulocytes, and deliver an optical PLT count (**PLT-O**; **Fig. 1**). Specifically, WBC counting and differentiation, as well as NRBC quantification, are carried out in the DIFF (differential) and WNB (WBC–NRBC–basophil) channels; reticulocyte enumeration and optical PLT counting are performed in the RET channel. A novel asymmetric cyanine fluorescent dye binds to nucleic acids within WBCs, and the fluorescence intensity reflects the extent of dye uptake, which is directly correlated to nucleic acid content. After RBC lysis, WBCs undergo structural changes depending on their type and maturation stage. Given that nucleic acid content varies among WBC subtypes and developmental stages, the binding of the fluorescent dye also differs.

The DIFF channel captures variations in scatter and fluorescence signals to differentiate lymphocytes, monocytes, neutrophils, and eosinophils, and to detect abnormal cells such as immature granulocytes, atypical lymphocytes, and blasts (**Fig. 2**). The WNB channel identifies basophils and NRBCs and performs total WBC counts (**Fig. 3**). In the RET channel, RBCs are not lysed but instead are sphered using a specific RET diluent. Fluorescent dyes then stain the nucleic acids within the sphered RBCs and PLTs, enabling quantification of reticulocytes and PLT-O (**Fig. 4**). In the final report, PLT-O is included when the reticulocyte count is performed; PLT-I is included when the CBC is performed without the reticulocyte count. For our study, a CBC with reticulocyte count was always performed; therefore, the data used for the comparison are the PLT-O.

Instrument calibration was executed by the manufacturer at the beginning of the study. The QC material (**QCM**) provided by the manufacturer includes 2 types of controls (one for all hematologic variables, one specifically for reticulocyte and PLT-O measurements) and 3 concentration levels (low, medium, high) for each control. These controls were run daily, and machine performance was confirmed using the QC rule 1_{2S} , which ensured that the results remained within acceptable limits (**Suppl. Table 1**).

A 2120i was run with the software (v. 6.11.7-MS). The functioning of the 2120i system has been described extensively in the literature and in the operator guide (**Table 1**).^{23,24} Daily internal QC was performed using human QCM at normal concentration (Advia 120/2120/2120i 3-in-1 TEST-point hematology control-normal; Siemens). Instrument calibration was carried out periodically as recommended by the manufacturer.

BC-75R Vet analytical performance assessment

Precision

Repeatability and reproducibility were assessed by calculating a within-run and between-run CV, respectively. To evaluate the repeatability (within-run precision), a fresh sample from a healthy patient was repeated 20 times within 1 h; reproducibility (between-run precision) was tested by measuring the QCM in duplicate each day for 20 consecutive working days. The CV was calculated as follows: $(SD/\bar{x}) \times 100\%$.

Linearity and carryover

Linearity was assessed for RBC, Hb, Ret, PLT, WBC, and WBC absolute differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils). Carryover was evaluated for RBC, WBC, PLT, and reticulocyte counts. A 10-mL pool was created to test both canine and feline blood samples, respectively, and centrifuged at $3,000 \times g$ for 10 min. After centrifugation,

the RBC-rich part was used as the 100% pool for testing RBC variables; the buffy coat was used as the 100% pool for assessing WBC and PLT variables. Plasma was used as the 0% pool to prepare serial dilutions of 25, 50, and 75%. All samples were measured in duplicate to test for linearity; carryover was evaluated by measuring the 100% pool twice and then measuring a PBS solution in triplicate.

Total error observed

To determine if the BC-75R Vet fulfilled the ASVCP veterinary quality requirements, the total error observed (TE_{obs}) for the main hematologic variables was assessed by the following formula: $TE_{obs} = 2CV + \text{bias}\%$.²⁰ For the TE_{obs} assessment of QCMs, we used $\text{bias}\%$ (systematic error) = (target values of the 3-level controls – mean value of the between-run results of respective level controls)/target values of the 3-level controls $\times 100\%$; CV (imprecision or random error) = $(SD/\bar{x}) \times 100\%$ of the between-run results of the 3-level controls. For TE_{obs} assessment of the samples of dogs and cats, we used $\text{bias}\%$ (systematic error) = (target values [that is, results from the 2120i] – mean value of the intra-assay results of BC-75R Vet); CV (imprecision or random error) = $(SD/\bar{x}) \times 100\%$ of within-run results of fresh samples from healthy patients.

Method comparison

Blood samples of animals presented at the VUH were included irrespective of medical conditions. All samples were first analyzed for clinical purposes with the 2120i, and then the CBC results were obtained with the BC-75R Vet. Samples were analyzed at room temperature and properly mixed before CBC testing. Manual WBC differential counts served as the reference method for WBC differential counts. Manual WBC differential count was performed by 4 operators (C. Agnoli, M. Baldin, S. Fasoli, K. Vasylyeva)—counting 100 leukocytes as reported

previously in each anonymized blood smear using the same optical microscope (BM80; Exacta Optech).²⁴ The mean WBC differential manual count was used.

Reference intervals

A population of healthy dogs and cats that underwent blood sampling for reasons other than our study (e.g., periodic health check, blood donor program, evaluation before elective surgery) was prospectively selected to establish the RI for CBC variables in the BC-75R Vet. Animals were deemed to be healthy based on signalment, history, clinical signs, and previous imaging, when available. Furthermore, no relevant abnormalities were detected in the 2120i CBC coupled with microscopic blood smear examination, in the serum chemistry profile (AU 480; Beckman Coulter), or in the urinalysis (Combur-Test 10 UX, Roche; Master refractometer, Atago). Blood donors also tested negative for infectious diseases according to the guidelines reported for blood donor screening.^{27,29}

Statistical analysis

Statistical analysis was performed using commercial software (Excel v.16.96.1, Microsoft; MedCalc Software, v. 19.4.1) adopting a significance threshold of $p < 0.05$ below which the data distribution was considered non-normal. Data were reported as $\bar{x} \pm SD$ or median and range (minimum-maximum values), depending on normal or non-normal distribution, respectively. Descriptive statistics were then used for age and CBC variables. Imprecision was evaluated by calculating $\bar{x}$, SD, and CVs. Linearity was assessed by comparing measured and expected (calculated) results with linear regression. The carryover percentage was calculated following the formula: $(B1-B3)/(A3-B3) \times 100\%$, where A was the 100% pool, B was the PBS solution, and the number after the letter A or B was the repetition.⁸

Spearman correlation, Passing–Bablok regression, and Bland–Altman analysis were used to compare the results of the 2 analyzers and the difference between the automated results and the manual counts. Based on previous studies, correlations were categorized according to the coefficient of determination (r^2) as excellent, r^2 of 0.93–0.99; good, r^2 of 0.80–0.92; moderate, r^2 of 0.59–0.79; and weak, $r^2 < 0.59$.^{4,11,20} Outliers were identified graphically and using the Passing–Bablok regression, and defined as residuals outside the 4 SD limit. In the Passing–Bablok regression, a proportional error was considered significant when the 95% CI of the slope did not include 1; a significant constant error was assumed when the CI of the intercept did not include 0; the potential clinical relevance of these errors was further evaluated based on our experience.

The RIs were calculated using parametric, nonparametric, or robust methods in accordance with the data distribution and the ASVCP guidelines.¹¹ Outliers in RI analysis were detected graphically and using the Tukey test. The normality of the data distribution was assessed by the Shapiro–Wilk test ($p < 0.2$ indicated a non-normal distribution).¹⁶ Bland–Altman limits of agreement (LOA) were calculated as percentiles [2.5, 97.5] when the distribution of the residuals was non-normal, and as mean difference ± 2 SD when the residuals were normally distributed according to the Shapiro–Wilk test ($p < 0.05$ indicated a non-normal distribution). The clinical acceptability of LOA, and thus the interchangeability of results between the 2 analyzers, was assessed by comparing the LOA with the ASVCP total allowable error (TE_a) when available, or based on our experience when TE_a values were not available for a given variable.

Results

BC-75R Vet performance measurement

Imprecision

Within-run CVs on patient samples for the main CBC variables were 0.28–8.39% for dogs and 0.37–25.2% for cats, respectively (**Table 2**). Between-run CVs on QCM results were 0.89–27.0%, 0.60–25.8%, and 0.8–33.4% for low, medium, and high concentrations, respectively (**Table 3**).

Linearity

The correlation between expected and measured values was excellent for RBCs, PLTs, neutrophils, lymphocytes, eosinophils, and reticulocytes in both dogs and cats, except for feline WBC and monocytes ($r = 0.91$ and $r = 0.84$, respectively), for which the correlation was good (**Table 4**).

Carryover

Carryover was 0% for all the variables tested (WBC, RBC, PLT, Ret), except for feline WBC, which had a 0.013% carryover effect.

Total error

The BC-75R Vet fulfilled the ASVCP veterinary quality requirements, given that its TE_{obs} were $<TE_a$ for the investigated hematologic variables for most of the QCM levels and for the patient samples (**Tables 5, 6**).²⁰ The TE_{obs} low-control level of neutrophils and high-control level of WBC was higher than the reference laboratory TE_a reported by ASVCP, but it was within the in-clinic TE_a .²⁰ Different results were obtained for the low-, medium-, and high-control levels for neutrophils, lymphocytes, monocytes, eosinophils, and basophils with a $TE_{obs} > TE_a$. The TE_{obs} for monocytes, eosinophils, and basophils were $>TE_a$ in both dogs and cats.

Method comparison

Demographics

We enrolled 411 dogs and 225 cats in this part of our study. The median age of the dogs included was 8.8 y (range 0.3–17.2 y). Of the selected dogs, 207 of 411 (50.4%) were females (150 of 411 [36.5%] were spayed females); 204 of 411 (49.6%) were males (87 of 411 [21.2%] were castrated males). Purebred dogs were 253 of 411 (57.4%), and mixed-breed dogs were 158 of 411 (42.6%). The median age of the cats included was 8.6 y (range 0.4–20.7 y). Of the selected cats, 78 of 225 (34.7%) were females (64 of 225 [28.4%] were spayed females); 147 of 225 (65.3%) were males (117 of 225 [52%] were castrated males). Purebred cats were 108 of 225 (21.3%), and mixed-breed cats were 117 of 225 (78.7%).

Agreement: regression and Bland–Altman

Agreement between analyzers in dogs was excellent for RBC, Hb, Hct, WBC, neutrophils (absolute count), and PLT count ($r^2 \geq 0.86$), with slopes and intercepts including 1 and 0 within their respective 95% CIs and narrow LOAs. Good agreement was observed for MCV, red cell distribution width (RDW), reticulocytes, plateletcrit (**PCT**), lymphocytes, eosinophils (absolute count), and leukocyte differential percentages for neutrophils and lymphocytes ($r^2 = 0.64$ – 0.85), with minor deviations of slope and intercept and acceptable LOAs. Moderate agreement was found for mean corpuscular hemoglobin (MCH), monocytes (absolute and percentage), and eosinophils (%; $r^2 = 0.35$ – 0.63), with increasing deviation of slope and intercept from ideal values and wider LOAs (**Figs. 5, 6; Suppl. Fig. 1**). MCHC and MPV had weak agreement ($r^2 < 0.35$), associated with marked slope deviation, intercept displacement, and broad limits of agreement.

In cats, excellent agreement was observed for RBC, Hb, Hct, WBC, and neutrophils (absolute count; $r^2 \geq 0.86$), with slopes and intercepts including 1 and 0 within their 95% CIs and narrow LOAs. Good agreement was found for MCV, MCH, RDW, PLT count, PCT, and

lymphocytes (absolute count; $r^2 = 0.64\text{--}0.85$), with minor analytical deviations. Moderate agreement was observed for leukocyte differentials ($r^2 = 0.35\text{--}0.63$), with wider LOAs (**Figs. 7, 8; Suppl. Fig. 2**). Weak agreement was found for MCHC, MPV, and reticulocytes ($r^2 < 0.35$), with relevant slope and intercept deviations and broad LOAs.

Agreement between automated analyzers and manual differential counts was lower overall. In both species, neutrophils and lymphocytes were in moderate agreement ($r^2 = 0.35\text{--}0.63$), with slopes >1 and intercepts <0 indicating proportional bias. Eosinophils were in moderate agreement ($r^2 = 0.35\text{--}0.63$) with limited bias. Monocytes were in weak agreement ($r^2 < 0.35$), with marked slope and intercept deviation and wide LOAs (**Tables 7, 8**).

Determination of RIs

We included 131 healthy dogs and 53 healthy cats in the reference population and calculated the RIs for CBC variables (**Table 9**). No animal was fully removed from the study. Up to 2 outliers in cats and up to 4 outliers in dogs were removed in a minority of analytes.

Discussion

Our comparison of the BC-75R Vet with the 2120i confirms the validity and feasibility for the routine use of the BC-75R Vet in a veterinary clinical pathology laboratory, for both dogs and cats.

The BC-75R Vet had excellent overall analytical performance when evaluated according to ASVCP guidelines and previously published validation studies for veterinary hematology analyzers.^{3,12,14,17,20} In particular, RBC-related variables, total WBC count, and PLT-related variables had robust precision, with within-run and between-run CVs $<5\%$, except for PLTs at the low QC level (CVs of 7.7–10.1%). The slightly higher variability observed at low PLT concentrations is not unexpected, as PLT enumeration, particularly at lower concentration, is a well-known analytical challenge in hematology.²⁶ However, this level of variability remains

clinically acceptable. The WBC differential counts had greater variability, with within-run CVs generally <10% but notably higher for feline monocytes (25.2%). This is consistent with the recognized limitations in accurately counting monocytes in cats, as highlighted in several studies, likely because of their morphologic heterogeneity and possible misclassification.^{3,7,31} Between-run CVs for differential counts were 3.3–33.4%, with the highest imprecision observed in monocyte and eosinophil counts. Neutrophils had the most consistent results with CVs <5%. Reticulocyte and NRBC counts also had higher between-run variability, particularly in the low QC level for reticulocytes (CV = 27.0%) and across all levels for NRBCs (14.9–25.8%), with a within-run CV <10% for reticulocytes. Although between-run variability contributed to increased imprecision, it is important to note that QCMs were used for this assessment, which may not represent the optimal matrix. Moreover, data on between-run variation in hematology are rarely reported, especially in veterinary medicine.^{3,14,28} Increased variability at low reticulocyte concentrations can be expected. Nevertheless, the within-run precision for reticulocytes was <10%, which is considered clinically acceptable compared to the expected thresholds in human medicine, given the lack of established veterinary-specific guidelines.⁸

Linearity analysis confirmed excellent correlation between measured and expected values for most variables ($r > 0.97$), both in canine and feline samples, and good correlation for feline PLTs and monocytes ($r = 0.91$ and $r = 0.84$, respectively). Strong linearity performance by this analyzer is a key requirement for clinical reliability and quantitative interpretation across a broad range of values. Carryover testing revealed negligible to no contamination between samples, with a 0% carryover for all variables except for feline WBCs, which had a minimal value of 0.013%, well below clinically relevant thresholds.

Overall, the BC-75R Vet met the precision, linearity, and carryover standards outlined in the ASVCP guidelines.¹ Although some limitations were observed (particularly in the feline monocyte count), the performance of the BC-75R Vet was comparable to other validated veterinary hematology analyzers and appears suitable for in-clinic and routine diagnostic use.^{3,12,14,15,20} Continued attention to cell-specific analytical challenges, particularly in cats, remains essential when interpreting differential counts, and blood smear review remains essential to confirm automated results.

Furthermore, the analyzer met the ASVCP analytical quality requirements, as TE_{obs} was lower than TE_a for the majority of hematologic variables assessed in dogs and cats.²⁰ The TE_{obs} of monocytes, eosinophils, and basophils exceeded the TE_a CLIA or in-clinic TE_a , but it might be lower than a TE_a derived from experts' opinions and medical decision levels for dogs and cats (a median TE_a of 60–90% has been proposed for normal eosinophil or monocyte counts).^{9,20} In contrast, the TE_{obs} for WBC types at all control levels exceeded the TE_a recommended for reference laboratories. Despite a $TE_{obs} > TE_a$ being reported for different QCM variables of various analyzers used in veterinary practice,⁹ our data were challenging to interpret, which might be related to the repeatability or stability of the controls. Given that the concentration of WBC types tended to decrease or increase gradually over the study period in all control levels (data not reported), it might be inferred that the analyzer counted them differently, that their morphology changed, or that the analyzer misclassified cell types, resulting in variable counts. These data can be interpreted considering the species-specific TE_{obs} . That is, the species-specific CV and bias may indicate effective performance of the analyzer in dogs and cats better than data obtained using human QCMs, especially for problematic variables (e.g., eosinophils).⁹ Similarly, TE_{obs} results might be improved by increasing the stability of the species-specific QCM. Despite

the difference in data yielded from control levels or healthy patients, in its entirety, our data support the suitability of this instrument for in-clinic use, where slightly wider analytical tolerance is acceptable. However, further studies are required to shed light on the possible causes of these different TE_{obs} .

Regarding comparisons of RBC-related variables, excellent correlations ($r^2 \geq 0.94$) were observed between the 2120i and the BC-75R Vet for RBCs, Hb, and Hct in both canine and feline samples with slopes close to 1, intercepts close to 0, and minimal bias. MCV also was in good agreement in both species ($r^2 = 0.88$), although in dogs a slope of 0.96 and an intercept of 4.09, with a bias of -1.1 fL (LOAs $[-3.5, 1.5]$), indicated a minor systematic deviation that may affect interpretation in borderline cases. For canine samples, MCHC had the greatest discrepancy, with weak correlation ($r^2 = 0.22$), a slope of 0.44, and a substantial positive intercept (18.8), suggesting combined proportional and systematic bias, as well as poor interchangeability between methods for this variable. In feline samples, the MCHC again had low agreement ($r^2 = 0.14$), a slope of 0.86, and a relatively high intercept (3.96), reinforcing concerns regarding this variable. The RDW in cats also had a statistically significant bias of -1.49% (95% CI: $[-3.20, -1.36]$), despite good correlation ($r^2 = 0.79$) and a slope close to 1, suggesting a constant negative bias.

Overall, although most RBC-related variables had acceptable agreement, MCHC and MCV (in dogs) and MCHC and RDW (in cats) warrant caution because of poor concordance. These differences underline the importance of method-specific RIs and highlight that systematic or proportional biases, even in the presence of strong correlation, can reduce clinical comparability. It is likely that discrepancies arise, at least in part, from the different methods employed by the 2 analyzers (i.e., impedance vs. laser-based methods), which may yield

divergent results. For example, the method used for the Hb measurement in the 2 analyzers is different; the 2120i uses a cyanide-based method, whereas the BC-75R Vet uses a cyanide-free method. An overestimation (as a proportional bias of approximately -20%) has been reported for dogs and cats in the Hb measurement with the cyanide-free method, and a bias of -15.8 to -23.9 mmol/L was observed for MCHC when comparing 120 and 2120 instruments, which used cyanine-based and cyanide-free methods, respectively.⁵ However, the authors of the above-mentioned study noted excellent correlation between the 2 methods for total Hb concentration,⁵ making it challenging to identify an explanation for this bias. MCHC is a well-known variable that increases when macroscopic alterations of serum occur, such as lipemia.¹⁰ Despite attempts to avoid processing samples with macroscopic lipemia, icterus, or hemolysis in our study, some undetected alterations might have resulted in a spurious increase in MCHC and a possible poor agreement between the different technologies used by the 2120i and the BC-75R Vet. Moreover, as MCHC is a calculated value, any bias in the measurement of variables used to obtain the MCHC can be propagated or even amplified in the final MCHC result, further contributing to the lack of agreement observed. The RBCs of dogs and cats have different susceptibilities to the lysing agent, resulting in various shapes, including incomplete or unsphered erythrocytes, which could provoke additional light reflection and lead to poor correlation between these 2 methods.^{5,25} However, further studies are needed to shed light on these findings.

The correlation between the 2120i and the BC-75R Vet was good to excellent (r^2 up to 0.98) for WBC-related variables for both species, with the exception of monocytes, which had discrepant results. The correlation was good ($r^2 = 0.73$ – 0.75) for the total count of monocytes by the 2 instruments in both species. However, different results were noted for the differential WBC count between the 2 analyzers and their comparison with manual counts in the 2 species. The

results obtained from dogs had lower systematic and proportional errors compared with those from cats, suggesting poor interchangeability between analyzers for this variable in cats. Inclusion in monocyte counts of cells with higher fluorescence activity, such as reactive lymphocytes or immature granulocytes, may result in an erroneous monocyte count and then poor agreement.⁴ We found similar disagreements when comparing the BC-75R Vet with manual counts for monocytes; the correlation was weak to moderate ($r^2 = 0.29\text{--}0.34$) in both cat and dog samples. These findings align with previous studies; monocytes have highly variable morphology and size, making their identification challenging even for fully trained operators, especially when toxic changes appear.^{4,24} Moreover, the negative bias observed in monocytes (% count = -1.04 in dogs, -1.20 in cats; $\times 10^9/\text{L}$ count = -0.12 in dogs, -0.17 in cats) and the positive bias noted in lymphocytes (% count = 3.88 in dogs, 2.76 in cats; $\times 10^9/\text{L}$ count = 0.34 in dogs, 0.33 in cats) obtained with the BC75-R in both species further corroborates a trend reported previously, in which monocyte counts are overestimated and lymphocyte counts are underestimated.^{4,31}

Similar to monocyte counts, the results that we obtained in dogs for both the differential and total counts of eosinophils showed better performance in terms of systematic, proportional errors, and interchangeability between the BC-75R Vet and the 2120i compared with those from cats. However, in cats, a slope of 1.00 in the differential count of eosinophils and an intercept of 0.002 in the total count of these cells indicated the absence of proportional and systematic error, respectively. This finding is understandable given that eosinophils could be clearly identified based on their internal structure and RNA content.⁴ Despite the good correlation between the 2 analyzers for feline eosinophils, the correlation with manual counts was slightly higher for the BC-75R Vet ($r^2 = 0.72$) than for the 2120i ($r^2 = 0.65$), suggesting good performance of the BC-

75R Vet in the detection of feline eosinophils. The BC-75R Vet performed better in dogs, considering the lower systematic (intercept 0.60 vs. 0.16) and proportional (slope 0.86 vs. 0.88) errors compared with manual counts in dogs. Different results have been presented for cats, reflecting a substantial tendency to underestimate eosinophil counts, despite the constant error being lower in the BC-75R Vet vs. manual counts (intercept 0.20) than in the 2120i vs. manual counts (intercept 0.25). Despite the difference in analytical performance, the performance in counting feline eosinophils was promising with the BC-75R Vet, given that counting these cells is challenging for some analyzers, including the 120 and 2120.⁴ Although monocytosis is found in association with various diseases, its impact on the diagnostic process is limited; in contrast, the detection of eosinophilia can significantly influence therapeutic decisions.⁶ Therefore, the evaluation of a blood smear by a trained operator remains the preferred method to assess the reliability of the WBC automated count, especially for some types of cells, such as monocytes and eosinophils.

The correlation of PLT and PCT was good to excellent ($r^2 = 0.86$ – 0.92), but the MPV correlation was fair to weak ($r = 0.001$ – 0.29) in both species. Remarkable differences were observed between dogs and cats for PLT counts. In dogs, the intercept (2.91) and slope (1.05) indicate minimal systematic error and almost absent proportional errors; however, the bias ($-17 \times 10^9/L$) and LOAs $[-86, 32]$ suggest that the 2 analyzers are not fully interchangeable. In cats, the intercept (19.0) and slope (0.92) indicate moderate systematic and proportional error. Moreover, the wide LOAs $[-127, 91]$ suggest that the 2 analyzers are not fully interchangeable, and caution should be exercised when interpreting counts in patients with borderline PLT counts. Additionally, it appeared that the BC-75R Vet tended to overestimate PLTs in dogs and in cats. A possible explanation for these discrepancies might rest on the technology used for PLT counts

in the BC-75R Vet, which is designed to de-aggregate PLT clumps.¹⁸ The optical fluorescence PLT counting technology of the BC-6800 (i.e., the BC-6800 human hematology analyzer shares the same PLT counting technology as the BC-75R Vet) has demonstrated a dissociation effect on human EDTA-dependent pseudo-thrombocytopenia and greater reliability of the optical fluorescence PLT counts in this setting.² The technology enables the de-aggregation of clumps by first pre-warming to 42°C, then mixing the blood and reagent at high speed with a vortex mixer, followed by counting via optical fluorescence.² We did not investigate or validate the dissociation effect of the BC-75R Vet on feline and canine PLT aggregates; further studies are needed to corroborate these results. The comparison results for MPV revealed severe systematic and proportional errors for both species, clearly indicating that the 2 analyzers are not interchangeable. Moreover, the weak correlation in cats renders the comparison between the BC-75R Vet and the 2120i undetectable. These data are not surprising given that the MPV is well-known as a challenging variable in cats.⁶ Giant PLT or small PLT aggregates, which occur frequently in cats, might be erroneously counted as RBCs.⁶ Despite electrical impedance-based analyzers being more affected, both MPV and PLT count could be inaccurate because PLT are prone to misclassification when aggregates are present. However, this erroneous count seems to occur irrespective of the methodology used, and the occurrence of PLT aggregates should be reduced in pre-analytical steps.^{6,13} Preanalytical and analytical factors cannot be completely ruled out when interpreting the feline PLT results despite efforts to exclude samples with clots or PLT aggregates.³⁰

Our study has some limitations that must be considered when interpreting our results. First, blood samples were analyzed within 3 h from collection, with a maximum of 1 h difference between analyzers, and the order of analyzers was not randomized; the 2120i was always used

first. Although this mode was in line with our routine, it may not fit perfectly with the routine of a commercial referral lab or other scenarios. Nevertheless, we do not believe that this timing had a significant impact on the validation results reported in our study. The non-randomized order of the 2 analyzers could introduce bias in interpreting the final results; however, the choice of 2120i first was necessary to guarantee a reliable patient diagnosis and comparability with previous lab tests in follow-ups. Second, between-run imprecision was evaluated using QCM, given its reported day-to-day stability. Although this material was not species-specific in our evaluation, its stability over several days made it the most suitable choice; its use in validating new instruments has been documented in the literature, and no simple alternative exists, to our knowledge. The number of cats selected for RI calculation was suboptimal (<120) compared with the ASVCP recommendation; however, this number can be considered adequate when related to the statistics used (robust method with 90% CI of RIs).¹¹ Finally, our study was not focused on validating the flags reported by the instrument and on the pre-analytical factor analysis; nevertheless, we tried to exclude all those samples with macroscopic alterations (i.e., severe lipemia, icterus, hemolysis) that could result in artefactual alterations of the CBC results, as reported in previous studies.

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BC75R-VET hematology analyzer and comparison with Siemens Advia 2120i: preliminary results for canine specimens. In: Proc 2024 ESVCP Congress, Budapest, HU, 2024:138).

Declaration of conflicting interests

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Supplemental material

Supplemental material for this article is available online.

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For Peer Review

Table 1. Summary of methodologies and channels of the BC-75R Vet and the 2120i.

Variable	BC-75R Vet		2120i	
	Channel	Method	Chamber	Method
RBC count, MCV, Hb content	RBC/PLT channel (RBC, PLT)	Electrical impedance	RBC/PLT reaction chamber (RBC, PLT)	Laser optical method (iso-volumetrically sphered RBCs pass in the flow cell)
HCT		Calculated		Calculated
CHCM	NA	NA	RBC/PLT reaction chamber (RBCs, PLTs)	Laser optical method; calculated based on RBC Hb concentration histogram
MCHC		Calculated		Calculated
MCH		Calculated		Calculated
MCV		Calculated based on RBC histogram		Calculated based on RBC histogram
Hb	Hb channel (Hb)	Cyanide-free Hb colorimetric method (measured by absorbance)	Hb reaction chamber (Hb)	Cyanide-based Hb colorimetric method
WBC total, WBC-D	WBC channel (Baso, NRBCs, WBC-N)	SF-Cube cell 3D analysis technology combining laser scatter and fluorescent signals; cells are identified by size (low-angle light scatter, forward laser scatter-FS), intracellular granularity (high-angle light scatter, side laser scatter-SS), and maturity stages (fluorescence signals-FL, produced by fluorescent dye-labeling nucleic acid)	Baso reaction chamber (WBCs, Baso)	WBCs, except the basophils, are stripped of their cytoplasm and subsequently categorized as mononuclear or polymorphonuclear cells based on their complexity and shape
	DIFF channel (Neu, Eos, Lymph, Mon, WBC-D)		Peroxo reaction chamber (WBCs, Neu, Lymph, Mon, Eos, LUC)	Identification of WBCs is based on size and intensity of peroxidase reaction, that depend on their levels of peroxidase activity
RET	RET channel (RET, WBC-R, PLT-O)	SF-Cube cell 3D analysis technology	Retic reaction chamber	Laser optical method
PLT	RBC/PLT channel (RBC, PLT)	Electrical impedance method (2 variables: PLT, PLT-I)	RBC/PLT reaction chamber (RBCs, PLTs)	Laser optical method (iso-volumetrically sphered PLTs pass in the flow cell)
PLT-O	RET channel (RET, WBC-R, PLT-O)	SF-Cube cell 3D analysis technology	NA	NA

Baso = basophils; CHCM = cellular hemoglobin concentration mean; DIFF = differential; Eos = eosinophils; LUC = large unstained cells; Lymph = lymphocytes; MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume; Mon = monocytes; NA = not available; Neu = neutrophils; NRBCs = nucleated RBCs; PLT = platelet; PLT-I = PLT count-impedance; PLT-O = optical PLT count; RET = reticulocytes; SF = scatter-fluorescence; WBC-D = WBC count-DIFF; WBC-N = WBC count-NRBC; WBC-O = optical WBC count; WBC-R = WBC count-RET.

For Peer Review

Table 2. Within-run imprecision of the BC-75R Vet hematology analyzer on canine and feline samples, for $n = 20$ repeats.

Variable	Dog		Cat	
	$\bar{x} \pm SD$	CV%	$\bar{x} \pm SD$	CV%
RBC, $\times 10^{12}/L$	5.56 ± 0.10	1.96	8.11 ± 0.05	0.69
Hct, L/L	0.40 ± 0.003	0.75	0.34 ± 0.003	0.8
Hb, g/L	138 ± 0.5	0.37	114 ± 0.4	0.4
MCV, fL	73 ± 0.2	0.28	44 ± 0.2	0.37
MCHC, g/L	341 ± 2	0.68	343 ± 5	0.7
MCH, pg	25 ± 0.2	0.66	15 ± 0.1	0.62
PLT-I, $\times 10^9/L$	229 ± 7	3.25	508 ± 15	2.99
PLT-O, $\times 10^9/L$	240 ± 10	4.24	397 ± 6	1.48
MPV, fL	9 ± 0.2	2.9	15 ± 0.2	1.55
WBC, $\times 10^9/L$	8.0 ± 0.3	3.4	6.1 ± 0.1	2.05
Neutrophils, $\times 10^9/L$	4.7 ± 0.3	6.22	2.2 ± 0.05	2.39
Lymphocytes, $\times 10^9/L$	2.5 ± 0.2	6.73	3.3 ± 0.1	2.62
Monocytes, $\times 10^9/L$	0.4 ± 0.02	6.88	0.1 ± 0.03	25.24
Eosinophils, $\times 10^9/L$	0.3 ± 0.02	8.39	0.4 ± 0.02	6.84
Reticulocytes, $\times 10^9/L$	51 ± 4	8.19	11 ± 1	9.07

MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration;

MCV = mean corpuscular volume; MPV = mean platelet volume; PLT-I = platelet count-impedance; PLT-O = platelet count-optical.

Table 3. Between-run imprecision of the BC-75R Vet hematology analyzer obtained from QC material at 3 concentration levels (low, medium, high).

Variable	Low		Medium		High	
	$\bar{x} \pm \text{SD}$	CV%	$\bar{x} \pm \text{SD}$	CV%	$\bar{x} \pm \text{SD}$	CV%
RBC, $\times 10^{12}/\text{L}$	2.32 ± 0.02	1.04	4.20 ± 0.03	0.88	6.16 ± 0.04	0.8
Hct, L/L	0.20 ± 0.003	1.28	0.40 ± 0.004	1.06	0.53 ± 0.01	0.92
Hb, g/L	61 ± 0.5	0.89	123 ± 0.7	0.60	162 ± 0.7	0.48
MCV, fL	85 ± 0.7	0.78	95 ± 0.7	0.70	100 ± 0.8	0.8
MCHC, g/L	306 ± 3	1.12	310 ± 3	1.02	310 ± 3	0.9
MCH, pg	26 ± 0.3	1.07	29 ± 0.3	0.91	31 ± 0.2	0.77
PLT-I, $\times 10^9/\text{L}$	56 ± 4	7.72	194 ± 5	2.79	383 ± 9	2.37
PLT-O, $\times 10^9/\text{L}$	99 ± 10	10.09	274 ± 13	4.85	490 ± 12	2.54
MPV, fL	13 ± 0.4	3.46	11 ± 0.2	1.78	12 ± 0.1	1.05
WBC, $\times 10^9/\text{L}$	3.8 ± 0.1	3.55	7.5 ± 0.2	1.99	19.3 ± 1.0	5.39
Neutrophils, $\times 10^9/\text{L}$	2.1 ± 0.1	4.21	4.0 ± 0.1	3.31	13.0 ± 0.4	3.36
Lymphocytes, $\times 10^9/\text{L}$	1.0 ± 0.04	4.86	2.2 ± 0.1	3.93	3.5 ± 1.1	25.7
Monocytes, $\times 10^9/\text{L}$	0.1 ± 0.01	16.07	0.3 ± 0.04	12.23	0.7 ± 0.2	33.39
Eosinophils, $\times 10^9/\text{L}$	0.6 ± 0.1	10.2	1.0 ± 0.1	9.48	2.0 ± 0.3	12.54
Reticulocytes, $\times 10^9/\text{L}$	63 ± 17	26.98	196 ± 14	7.22	171 ± 9	5.25
NRBC, $\times 10^9/\text{L}$	0.3 ± 0.06	17.51	0.3 ± 0.1	25.79	0.5 ± 0.1	14.86
NRBC/100 WBC	9.2 ± 1.4	15.69	4.2 ± 1.0	23.75	2.7 ± 0.4	15.44

MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration;

MCV = mean corpuscular volume; MPV = mean platelet volume; NRBC = nucleated RBCs;

PLT-I = platelet count-impedance; PLT-O = platelet count-optical.

Table 4. Linearity test and respective measuring range of the BC-75R Vet hematology analyzer.

Variable	Dog				Cat			
	MR	<i>r</i>	I	S	MR	<i>r</i>	I	S
RBC, ×10 ¹² /L	0.02–9.46	0.97	–0.09	0.92	0.11–15.3	0.99	–0.30	1.00
PLT, ×10 ⁹ /L	272–3,077	0.99	–370	1.08	484–918	0.99	–775	1.91
WBC, ×10 ⁹ /L	0.05–53.8	0.97	1.0	1.79	0.4–51.5	0.91	–0.3	0.98
Neutrophils, ×10 ⁹ /L	0.02–34.3	0.97	1.0	1.32	0.2–30.1	0.99	–0.1	0.99
Lymphocytes, ×10 ⁹ /L	0.02–16.5	0.98	1.0	0.31	0.2–18.2	0.99	–0.1	1.00
Monocytes, ×10 ⁹ /L	0.02–0.2	0.97	1.0	0.02	0.01–1.3	0.84	0.03	0.81
Eosinophils, ×10 ⁹ /L	0.0–1.3	0.95	0.9	0.01	0.01–2.4	0.97	–0.05	0.94
Reticulocytes, ×10 ⁹ /L	0–20	0.98	–1	0.96	0–19	0.98	–1	1.02

I = intercept; MR = measuring range; PLT = platelets; *r* = correlation coefficient; S = slope.

Table 5. Bias, CV, and total observed error (TE_{obs}) for 3 concentrations of QC material (QCM) for the main hematology variables.

		QCM																				TE _a		
		Low				Medium								High										
Variable	<i>n</i>	TM	AI	CM	SD	Bias %	CV %	TE _{obs} %	TM	AI	CM	SD	Bias %	CV %	TE _{obs} %	TM	AI	CM	SD	Bias %	CV %	TE _{obs} %	ASVCP	CLIA
RBC, ×10 ¹² /L	40	2.38	2.20–2.56	2.32	0.02	2.48	1.05	4.58	4.29	4.05–4.53	4.21	0.04	1.87	0.89	3.64	5.31	5.01–5.61	5.17	0.04	2.70	0.81	4.31	10	6
Hb, g/L	40	6	6–7	6	0.05	0.66	0.90	2.46	12	12–13	12	0.07	0.46	0.61	1.67	16	16–17	16	0.08	0.90	0.49	1.88	10	7
Hct, L/L	40	0.21	0.19–0.23	0.20	0.03	3.43	1.29	6.00	0.41	0.38–0.43	0.40	0.04	1.72	1.06	3.84	0.53	0.50–0.56	0.52	0.05	2.46	0.92	4.30	10	6
MCV, fL	40	86	81–91	85	0.67	0.80	0.79	2.38	95	90–100	95	0.67	−0.05	0.71	1.46	101	96–106	101	0.81	−0.30	0.80	1.90	7	NA
MCHC, g/L	40	298	268–328	306	3	−2.78	1.12	5.02	31	28–34	31	0.32	−1.33	1.02	3.38	31	28–34	31	0.28	−1.70	0.90	3.50	10	NA
WBC, ×10 ⁹ /L	40	3.51	2.71–3.31	3.79	0.13	−8.03	3.56	15.1	7.37	6.37–8.37	7.51	0.15	−1.96	2.00	5.96	21.17	18.7–23.7	19.30	1.04	8.82	5.39	19.6	15; 20*	15
Neu, ×10 ⁹ /L	40	1.97	1.74–2.47	2.12	0.09	−7.56	4.22	16.0	3.58	2.78–4.38	3.98	0.13	−11.16	3.32	17.8	11.69	9.61–13.8	13.0	0.44	−11.43	3.37	18.19		
Mon, ×10 ⁹ /L	40	0.13	0.0–0.3	0.11	0.02	17.88	16.07	50.0	0.38	0.0–0.83	0.33	0.04	12.50	12.24	37.0	0.95	0.0–2.51	0.66	0.22	30.63	33.39	97.42		
Eos, ×10 ⁹ /L	40	0.44	0.14–0.74	0.59	0.06	−33.8	10.2	54.2	0.60	0.06–1.14	0.97	0.09	−61.79	9.48	80.8	1.35	0.1–2.6	2.02	0.25	−49.72	12.55	74.82		
Baso, ×10 ⁹ /L	40	0.05	0.0–0.15	0.02	0.01	56.50	37.37	131	0.1	0.0–0.2	0.07	0.03	111	40.04	111	0.28	0.0–0.57	0.13	0.02	52.14	17.70	87.56		
PLT, ×10 ⁹ /L	40	53	33–73	56	4	−6.42	7.72	21.9	202	157–247	194	5	4.07	2.79	9.66	402	337–467	383	9	4.80	2.38	9.56	20; 25*	25

AI = acceptable intervals; ASVCP = American Society for Veterinary Clinical Pathology; Baso = basophils; CLIA = Clinical Laboratory

Improvement Amendments; CM = calculated mean; Eos = eosinophils; Lym = lymphocytes; MCHC = mean corpuscular hemoglobin concentration;

MCV = mean corpuscular volume; NA = not available; Neu = neutrophils; Mon = monocytes; PLT = platelets; TE_a = total allowable error; TM =

target mean. Boldface indicates that the TE_a percent value exceeds the allowed limit.

* Reference laboratory; in-clinic TE_a.¹⁹

Table 6. Bias, CV, and total observed error (TE_{obs}) for samples from dogs and cats for the main hematology variables.

Variable	n	Dog						Cat						TE _a	
		TM	CM	SD	Bias %	CV %	TE _{obs} %	TM	CM	SD	Bias %	CV %	TE _{obs} %	ASVCP	CLIA
RBC, ×10 ¹² /L	20	5.85	5.54	0.04	5.28	0.68	6.64	7.88	7.71	0.06	2.11	0.73	3.56	10	6
Hb, g/L	20	15	14	0.05	4.97	0.38	5.72	12	12	0.05	1.93	0.4	2.74	10	7
Hct, L/L	20	0.41	0.40	0.30	2.22	0.75	3.72	0.34	0.34	0.03	−0.65	0.8	2.25	10	6
MCV, fL	20	71	73	0.21	−3.09	0.28	3.65	43	44	0.17	−2.80	0.38	3.55	7	NA
MCHC, g/L	20	34	34	0.24	0.23	0.69	1.61	35	34	0.24	2.86	0.71	4.28	10	NA
WBC, ×10 ⁹ /L	20	8.00	7.72	0.13	3.56	1.72	7.00	6.52	6.09	0.11	6.66	1.73	10.13	15; 20*	15
Neu, ×10 ⁹ /L	20	4.75	4.55	0.11	4.15	2.49	9.14	2.31	2.23	0.05	3.51	2.40	8.30		
Lym, ×10 ⁹ /L	20	2.70	2.50	0.07	7.41	2.78	13.0	3.64	3.34	0.09	8.23	2.62	13.47		
Mon, ×10 ⁹ /L	20	0.27	0.35	0.02	−28.89	6.89	42.7	0.12	0.13	0.03	−9.17	25.24	59.7		
Eos, ×10 ⁹ /L	20	0.27	0.31	0.03	−13.15	8.39	29.9	0.44	0.38	0.03	14.09	6.85	27.8		
Baso, ×10 ⁹ /L	20	0.01	0.01	0.00	5.00	23.54	52.1	0.0	0.01	0.00	ND	37.5	ND		
PLT, ×10 ⁹ /L	20	249	240	10.20	3.53	4.25	12.0	438	397	5.91	9.36	1.49	12.3	20; 25*	25

ASVCP = American Society for Veterinary Clinical Pathology; Baso = basophils; CLIA = Clinical Laboratory Improvement Amendments; CM = calculated mean; Eos = eosinophils; Lym = lymphocytes; MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume; NA = not available; ND = not determined; Neu = neutrophils; Mon = monocytes; PLT = platelets; TE_a = total allowable error; TM = target mean. Boldface indicates that the TE_a percent value exceeds the allowed limit.

* Reference laboratory; in-clinic TE_a.¹⁹

Table 7. Agreement between the 2120i and the BC-75R Vet hematology analyzers. The reported data include the intercept and slope of the Passing–Bablok regression, as well as the bias (difference between the mean measurements of the 2120i used as reference method, and the BC-75R Vet). Limits of agreement (LOAs) are expressed as ± 2 SD for normally distributed differences ($p > 0.05$; marked with an asterisk after the bias) and as the 2.5th–97.5th percentiles for non-normal distributions ($p < 0.05$). The p -value from the Cusum test for linearity was 0.05 for all these variables.

Variable	Dog				Cat			
	r^2	S [95% CI]	I [95% CI]	Bias [LOA]	r^2	S [95% CI]	I [95% CI]	Bias [LOA]
RBC, $\times 10^{12}/L$	0.96	1.02 [1.00, 1.04]	−0.41 [−0.52, −0.29]	0.251 [−0.290, 0.680]	0.96	1.01 [0.99, 1.03]	−0.22 [−0.36, −0.06]	0.140 [−0.545, 0.775]
Hb, g/L	0.98	1.00 [1.00, 1.01]	−0.30 [−0.43, −0.30]	0.272 [−0.400, 0.900]	0.98	1.00 [0.98, 1.00]	−0.30 [−0.30, −0.04]	0.316 [−0.340, 1.30]
Hct, L/L	0.94	1.04 [1.01, 1.06]	−3.13 [−4.11, −2.16]	1.1 [−3.6, 4.4]	0.94	1.00 [0.96, 1.02]	0.10 [−0.70, 1.08]	0.1* [−3.5, 3.6]
MCV, fL	0.88	0.96 [0.92, 1.00]	4.09 [1.20, 6.43]	−1.1 [−3.5, 1.5]	0.88	1.05 [1.00, 1.10]	−1.60 [−3.66, 0.70]	−0.7* [−3.2, 1.8]
MCHC, g/L	0.22	0.44 [0.38, 0.50]	18.79 [16.95, 20.64]	−3 [−25, 28]	0.14	0.86 [0.70, 1.00]	3.96 [−0.90, 9.03]	9* [−20, 37]
MCH, pg	0.62	0.91 [0.85, 0.97]	2.75 [1.36, 3.94]	−0.58* [−2.12, 0.95]	0.86	1.00 [0.92, 1.00]	−0.10 [−0.10, 0.95]	0.12 [−0.90, 1.04]
RDW, %	0.79	1.00 [0.92, 1.00]	0.70 [0.70, 1.71]	−0.7 [−1.7, 0.6]	0.79	1.07 [1.00, 1.14]	0.24 [−0.85, 1.45]	−1.49 [−3.20, −1.36]
Reticulocytes, $\times 10^9/L$	0.77	0.97 [0.93, 1.00]	−1.23 [−3.2, 4.75]	4.9 [−22.6, 49.2]	0.04	30.6 [22.6, 47.0]	−0.48 [−0.75, −0.34]	−9.6 [−68.2, 13.7]
PLT, $\times 10^9/L$	0.92	1.05 [1.02, 1.06]	2.91 [−2.3, 7.3]	−17 [−86, 32]	0.86	0.92 [0.88, 0.94]	19.00 [9.44, 26.92]	−4 [−127, 91]
MPV, fL	0.29	0.67 [0.60, 0.75]	3.05 [2.20, 3.85]	0.8 [−2.0, 5.2]	0.001	0.18 [0.11, 0.25]	12.90 [11.67, 13.88]	0.9 [−5.8, 11.6]
PCT, %	0.82	0.90 [0.86, 0.94]	0.04 [0.02, 0.05]	0.01 [−0.13, 0.17]	0.72	1.21 [1.13, 1.29]	−0.05 [−0.07, −0.02]	−0.03 [−0.27, 0.24]
WBC, $\times 10^9/L$	0.98	1.01 [0.99, 1.01]	−0.098 [−1.74, 6.84]	0.060 [−0.93, 1.0]	0.98	1.01 [0.99, 1.02]	−0.10 [−0.21, 0.02]	0.096 [−0.99, 1.70]
Neutrophils, %	0.90	1.00 [0.97, 1.01]	2.82 [1.58, 4.23]	−3.3 [−13.5, 0.9]	0.79	1.01 [0.97, 1.04]	1.18 [−1.30, 4.09]	−2.1 [−22.9, 11.9]
Lymphocytes, %	0.86	0.95 [0.91, 0.97]	−2.08 [−2.83, −1.37]	3.9 [−1.0, 13.0]	0.82	1.03 [0.99, 1.06]	−3.37 [−4.51, −2.44]	2.8 [−10.3, 13.9]
Monocytes, %	0.50	1.13 [1.04, 1.23]	0.43 [−0.01, 0.82]	−1.0 [−5.2, 3.4]	0.40	1.70 [1.5, 2]	−0.52 [−1.05, 0.00]	−1.2 [−5.5, 2.0]
Eosinophils, %	0.79	1.05 [1.02, 1.06]	−0.27 [−0.35, −0.20]	0.0 [−2.5, 1.9]	0.72	1.00 [0.93, 1.05]	−0.10 [−0.28, 0.21]	0.2 [−3.8, 6.0]
Neutrophils, $\times 10^9/L$	0.98	1.03 [1.01, 1.03]	0.05 [−0.01, 0.12]	−0.29 [−2.0, 0.50]	0.96	1.02 [1.00, 1.04]	−0.02 [−0.14, 0.11]	−0.15 [−2.56, 1.32]
Lymphocytes, $\times 10^9/L$	0.79	0.94 [0.90, 0.96]	−0.16 [−0.21, 0.11]	0.34 [−0.16, 1.2]	0.81	1.00 [0.95, 1.04]	−0.30 [−0.41, −0.20]	0.33 [−0.64, 1.28]
Monocytes, $\times 10^9/L$	0.75	1.14 [1.09, 1.20]	0.04 [0.01, 0.06]	−0.11 [−0.57, 0.23]	0.73	1.64 [1.50, 1.80]	−0.03 [−0.05, 0.00]	−0.17 [−0.70, 0.06]
Eosinophils, $\times 10^9/L$	0.82	1.05 [1.01, 1.07]	−0.03 [−0.04, −0.02]	0.021 [−0.16, 0.21]	0.68	0.96 [0.89, 1.02]	0.002 [−0.02, 0.03]	0.01 [−0.38, 0.36]

I = intercept; MCH = mean corpuscular hemoglobin, MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume;

MPV = mean platelet volume; PCT = plateletcrit; PLT = platelet count; r = Spearman rho; RDW = red cell distribution width; S = slope.

Table 8. Agreement of WBC differential counts between manual and automated 2120i or between manual and BC-75R Vet hematology analyzer. The reported data include the intercept and slope of the Passing–Bablok regression, as well as the bias between the mean measurements of the manual count, which serves as the reference method, and the 2120i, along with the comparison between the manual count and the Mindray BC-75R Vet automated counts. Limits of agreement (LOAs) are expressed as ± 2 SD for normally distributed differences ($p > 0.05$; marked with an asterisk after the bias) and as the 2.5th–97.5th percentiles for non-normal distributions ($p < 0.05$). The p -value from the Cusum test for linearity was > 0.05 for all these variables.

		Dog							
		Manual count vs. 2120i				Manual count vs. BC-75R Vet			
Variable, %	<i>n</i>	<i>r</i> ²	S [95% CI]	I [95% CI]	Bias [LOA]	<i>r</i> ²	S [95% CI]	I [95% CI]	Bias [LOA]
Neutrophils	346	0.82	1.07 [1.02, 1.12]	−9.48 [−13.04, −5.74]	4.3 [−6.7, 17.2]	0.77	1.06 [1.01, 1.11]	−5.56 [−9.26, −2.17]	0.82 [−12.2, 13.5]
Lymphocytes	346	0.82	1.17 [1.11, 1.22]	3.32 [2.59, 4.05]	−5.7 [−15.0, 1.64]	0.79	1.10 [1.04, 1.15]	0.60 [−0.07, 1.38]	1.83 [−11.0, 6.4]
Monocytes	346	0.37	0.60 [0.51, 0.66]	0.80 [0.37, 1.24]	2.1 [−3.6, 8.3]	0.34	0.70 [0.61, 0.80]	1.10 [0.50, 1.70]	1.1 [−5.0, 7.3]
Eosinophils	346	0.67	0.86 [0.80, 0.91]	0.60 [0.50, 0.70]	−0.04 [−3.4, 4.1]	0.72	0.88 [0.83, 0.92]	0.16 [0.10, 0.27]	0.1 [−3.7, 4.0]
		Cat							
		Manual count vs. 2120i				Manual count vs. BC-75R Vet			
Variable, %	<i>n</i>	<i>r</i> ²	S [95% CI]	I [95% CI]	Bias [LOA]	<i>r</i> ²	S [95% CI]	I [95% CI]	Bias [LOA]
Neutrophils	209	0.75	1.10 [1.03, 1.16]	−10.53 [−15.78, −5.79]	3.7 [−10.2, 17.7]	0.81	1.10 [1.05, 1.15]	−9.57 [−13.08, −5.90]	1.5 [−10.8, 12.2]
Lymphocytes	209	0.77	1.17 [1.09, 1.26]	2.42 [1.13, 3.55]	−4.9 [−17.2, 7.2]	0.82	1.17 [1.11, 1.22]	−0.59 [−1.36, 0.31]	−2.1 [−11.8, 9.2]
Monocytes	209	0.20	0.48 [0.38, 0.60]	0.64 [0.30, 1.05]	1.1 [−2.2, 6.5]	0.29	0.85 [0.72, 1.00]	0.65 [0.20, 1.08]	−0.1 [−4.2, 4.1]
Eosinophils	209	0.65	0.86 [0.80, 0.92]	0.25 [0.00, 0.50]	0.5 [−4.0, 6.4]	0.72	0.83 [0.78, 0.89]	0.20 [0.05, 0.35]	0.8 [−2.8, 4.8]

I = intercept; *n* = number of samples; *r* = Spearman rho; S = slope.

Table 9. RIs for the main CBC variable results determined with the BC-75R Vet. The RIs were reported according to the calculated method used, following the ASVCP guidelines: parametric (Par), robust (Rob), or non-parametric (Nopar) methods.

Variable	Cat					Dog				
	<i>n</i>		LL [90% CI]	UL [90% CI]	2120i internal RI	<i>n</i>		LL [90% CI]	UL [90% CI]	2120i internal RI
WBC, $\times 10^9/L$	53	Rob	4.0 [3.6, 4.5]	16.4 [14.3, 18.5]	4.8–14.9	130	Nopar	4.7 [4.4, 5.1]	14.3 [12.5, 14.5]	5.0–14.0
		Nopar	4.4 [ND]	15.1 [ND]						
Neutrophils, $\times 10^9/L$	53	Rob	1.6 [1.3, 1.8]	11.7 [9.7, 13.8]	1.6–10.0	130	Nopar	2.8 [2.7, 3.2]	9.6 [9.0, 12.0]	3.0, 10.0
		Nopar	4.4 [ND]	15.1 [ND]						
Lymphocytes, $\times 10^9/L$	53	Rob	0.8 [0.7, 1.1]	8.7 [7.0, 11.1]	0.9–5.6	127	Nopar	0.9 [0.7, 1.1]	3.8 [3.2, 4.2]	0.9–4.0
		Nopar	0.6 [ND]	7.8 [ND]						
Monocytes, $\times 10^9/L$	53	Rob	0.1 [0.1, 0.1]	0.7 [0.5, 0.8]	0.0–0.7	130	Nopar	0.2 [0.2, 0.3]	0.9 [0.8, 1.2]	0.1–1.0
		Nopar	0.1 [ND]	0.6 [ND]						
Eosinophils, $\times 10^9/L$	52	Rob	0.1 [0.1, 0.2]	1.2 [0.9, 1.5]	0.1–1.5	131	Nopar	0.1 [0.1, 0.2]	1.4 [1.1, 1.6]	0.0–1.1
		Nopar	0.1 [ND]	1.2 [ND]						
RBC, $\times 10^{12}/L$	53	Par	7.0 [6.7, 7.4]	10.3 [10.0, 10.7]	7–11	130	Nopar	5.3 [5.0, 5.5]	8.2 [7.9, 8.6]	5.7–8.4
MCV, fL	53	Par	37 [36, 39]	51 [50, 52]	36–55	130	Nopar	67 [66, 67]	78 [77, 78]	63–77
Hb, g/L	53	Par	108 [103, 112]	155 [150, 160]	100–160	129	Nopar	131 [115, 138]	200 [191, 215]	140–190
Hct, L/L	52	Par	0.3 [0.3, 0.3]	0.5 [0.4, 0.5]	0.3–0.5	129	Nopar	0.4 [0.3, 0.4]	0.6 [0.6, 0.6]	0.4–0.6
MCH, pg	53	Rob	13 [12, 13]	17 [17, 18]	12–16	129	Nopar	23 [22, 23]	26 [26, 27]	22–26
		Nopar	13 [ND]	17 [ND]						
MCHC, g/L	53	Par	322 [318, 326]	364 [360, 368]	310–360	128	Nopar	329 [328, 333]	349 [347, 355]	320–370
PLT, $\times 10^9/L$	51	Rob	108 [77, 136]	449 [411, 481]	150–500	129	Nopar	147 [136, 167]	440 [392, 474]	150–500
		Nopar	156 [ND]	474 [ND]						
MPV, fL	53	Par	13 [12, 13]	18 [18, 19]	8–26	129	Nopar	8 [8, 9]	13 [13, 14]	8–14
PCT, L/L	53	Par	0.2 [0.1, 0.2]	0.7 [0.6, 0.7]	NA	129	Nopar	0.2 [0.2, 0.2]	0.4 [0.4, 0.5]	0.1–0.4
Reticulocytes, $\times 10^9/L$	53	Rob	7 [6, 9]	58 [47, 71]	0–80	129	Nopar	10 [7, 13]	96 [86, 110]	0–120
		Nopar	5 [ND]	55 [ND]						

LL = lower limit; MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume;

MPV = mean platelet volume; NA = not available; ND = cannot be determined; PCT = plateletcrit; PLT = platelets; UL = upper limit.

Figure 1. The SF-Cube technology enables 3-dimensional analysis by combining laser light scatter at 2 angles with fluorescence signals (low-angle scatter for cell size, high-angle scatter for intracellular granularity). This analysis is used to perform total and differential WBC counts, quantify nucleated RBCs and reticulocytes, and deliver an optical platelet count (¹⁹ modified).

Figure 2. In the DIFF channel, the difference signals in the 3-dimensional analysis of the cells are differentiated, and the subpopulations of WBCs, abnormal cells (immature granulocytes, abnormal lymphocytes), and blast cells are graphed accordingly in the DIFF scattergram. FL = fluorescence intensity; SS = side scatter (¹⁹ modified).

Figure 3. The WNB channel identifies basophils and nucleated RBCs, performs total WBC count, and graphs them accordingly in the WNB scattergram. FL = fluorescence intensity; FS = cell volume (¹⁹ modified).

Figure 4. Three scattergrams for reticulocyte count: **A)** reticulocyte scattergram; **B)** reticulocytes–extension scattergram; **C)** optical platelet count. Fluorescent dyes stain the nucleic acids within the sphered RBCs and platelets, enabling quantification of reticulocytes (A, B) and platelets (C). FL = fluorescence intensity; FS = cell volume (¹⁸ modified).

Figure 5. Agreement of RBCs, Hct, Hb, and mean corpuscular volume (MCV) obtained with the 2120i and the BC-75R Vet hematology analyzers for canine samples. **A–D.** Passing–Bablok regression analyses. Dotted black line = identity line ($x = y$); solid black line = regression line. **E–H.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

Figure 6. Agreement of WBC and platelet (PLT) counts obtained with the 2120i and the BC-75R Vet hematology analyzers for 411 canine samples. **A, B.** Passing–Bablok regression analysis. Dotted black line = identity line ($x = y$); solid black line = regression line. **C, D.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers.

Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

Figure 7. Agreement of RBC, Hct, Hb, and mean corpuscular volume (MCV) obtained with 2120i and BC-75R Vet hematology analyzers for 225 feline samples. **A–D.** Passing–Bablok regression analysis. Dotted black line = identity line ($x=y$); solid black line = regression line. **E–H.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

Figure 8. Agreement of WBC and platelet (PLT) counts obtained with 2120i and BC-75R Vet hematology analyzers for 225 feline samples. **A, B.** Passing–Bablok regression analysis. Dotted black line = identity line ($x = y$); solid black line = regression line. **C, D.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

Supplemental Table 1; Supplemental Figures 1, 2.

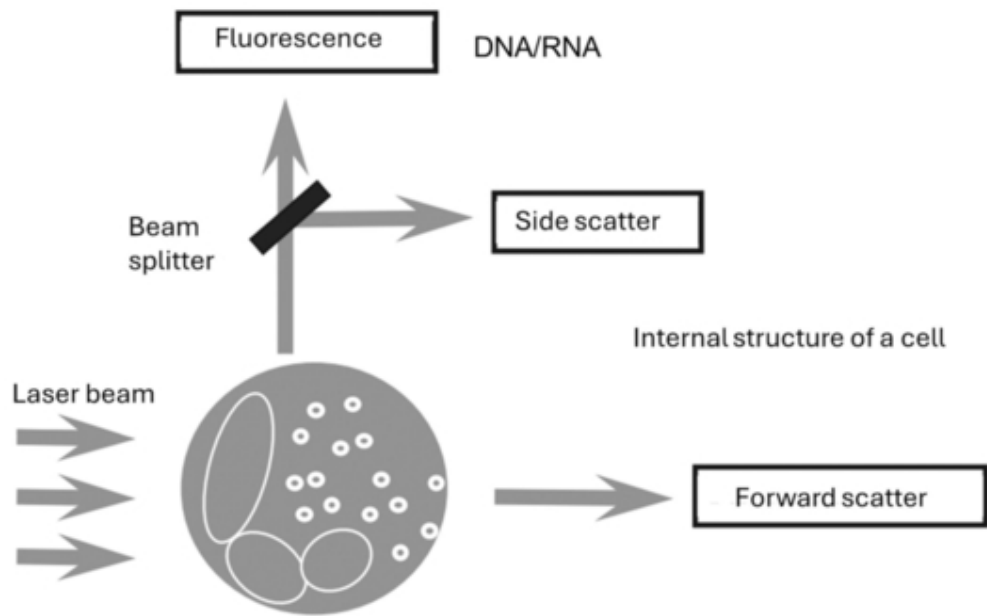


Figure 1. The SF-Cube technology enables 3-dimensional analysis by combining laser light scatter at 2 angles with fluorescence signals (low-angle scatter for cell size, high-angle scatter for intracellular granularity). This analysis is used to perform total and differential WBC counts, quantify nucleated RBCs, reticulocytes, and deliver an optical platelet count (¹⁹ modified).

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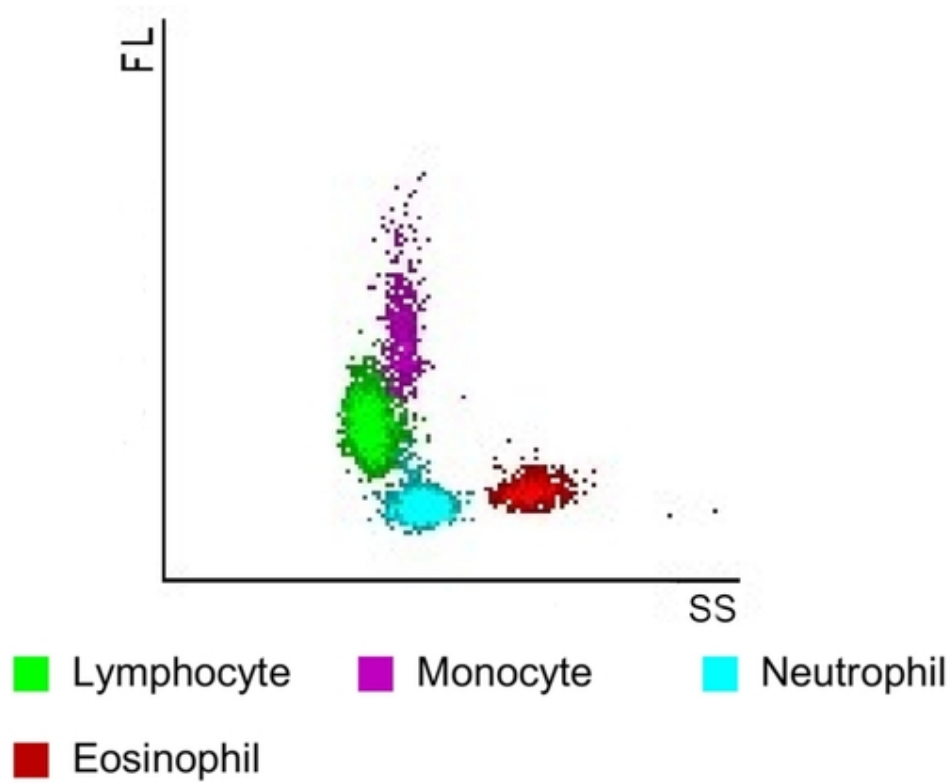


Figure 2. In the DIFF channel, the difference signals in the 3-dimensional analysis of the cells are differentiated, and the subpopulations of WBCs, abnormal cells (immature granulocytes, abnormal lymphocytes), and blast cells are graphed accordingly in the DIFF scattergram. FL = fluorescence intensity; SS = side scatter (¹⁹ modified).

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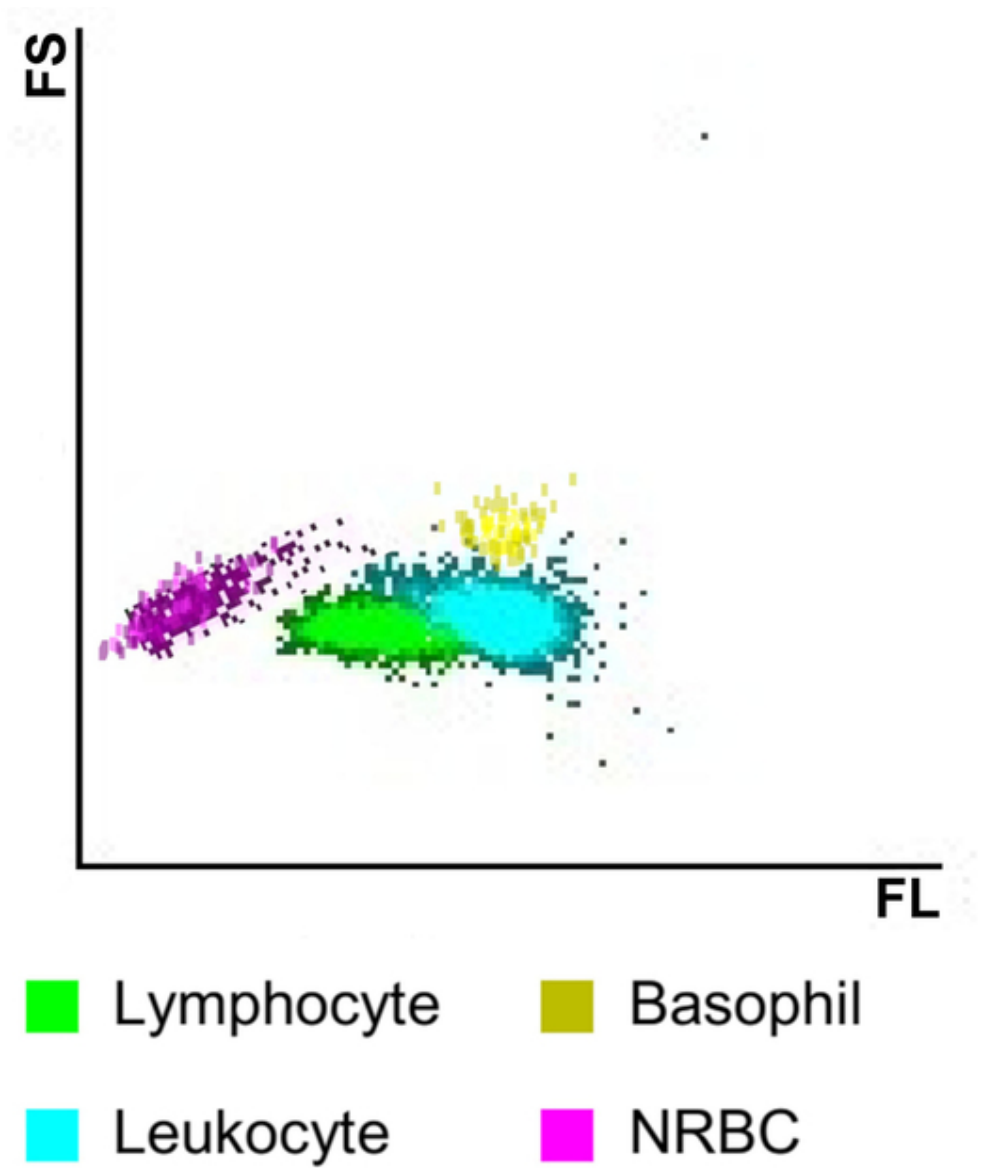


Figure 3. The WNB channel identifies basophils and nucleated RBCs, performs total WBC count, and graphs them accordingly in the WNB scattergram. FL = fluorescence intensity; FS = cell volume (¹⁹ modified).

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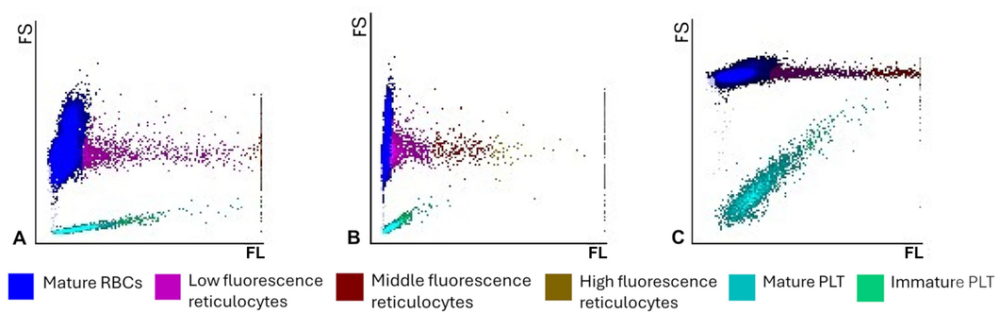


Figure 4. Three scattergrams for reticulocyte count: **A)** reticulocyte scattergram; **B)** reticulocytes-extension scattergram; **C)** optical platelet count. Fluorescent dyes stain the nucleic acids within the sphered RBCs and platelets, enabling quantification of reticulocytes (A, B) and platelets (C). FL = fluorescence intensity; FS = cell volume (¹⁸ modified).

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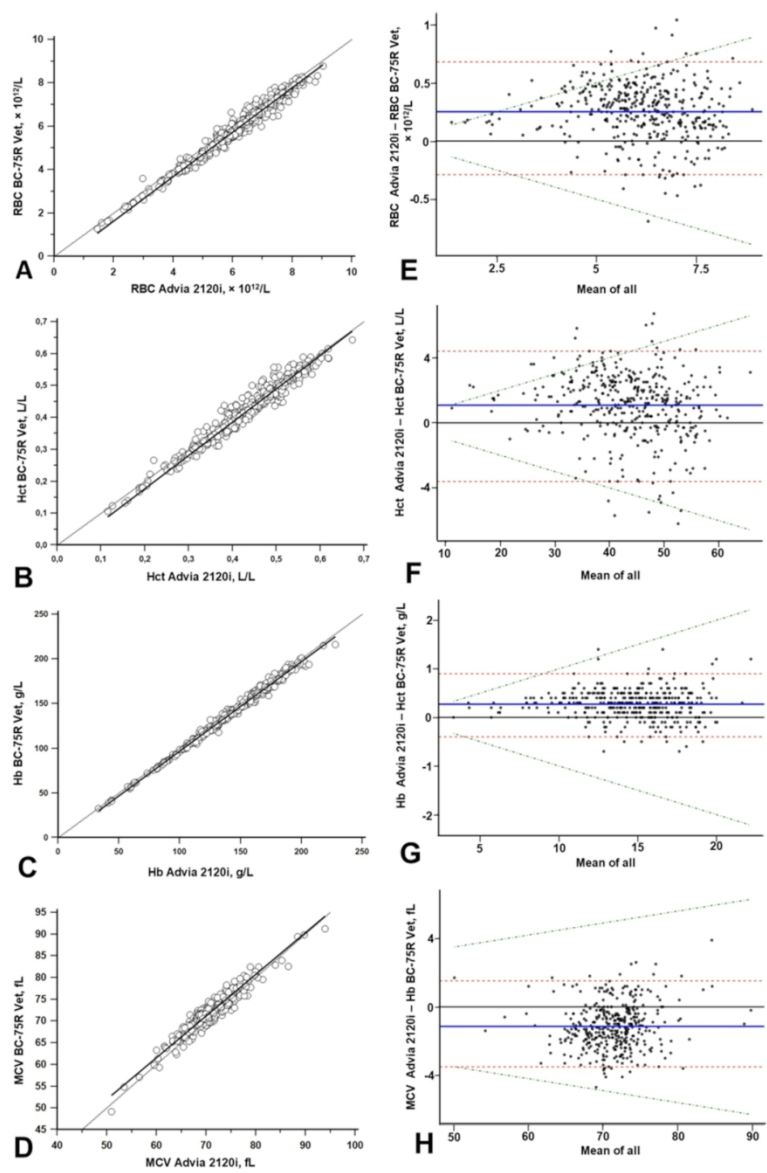


Figure 5. Agreement of RBCs, Hct, Hb, and mean corpuscular volume (MCV) obtained with the 2120i and the BC-75R Vet hematology analyzers for canine samples. **A–D.** Passing–Bablok regression analyses. Dotted black line = identity line ($x = y$); solid black line = regression line. **E–H.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

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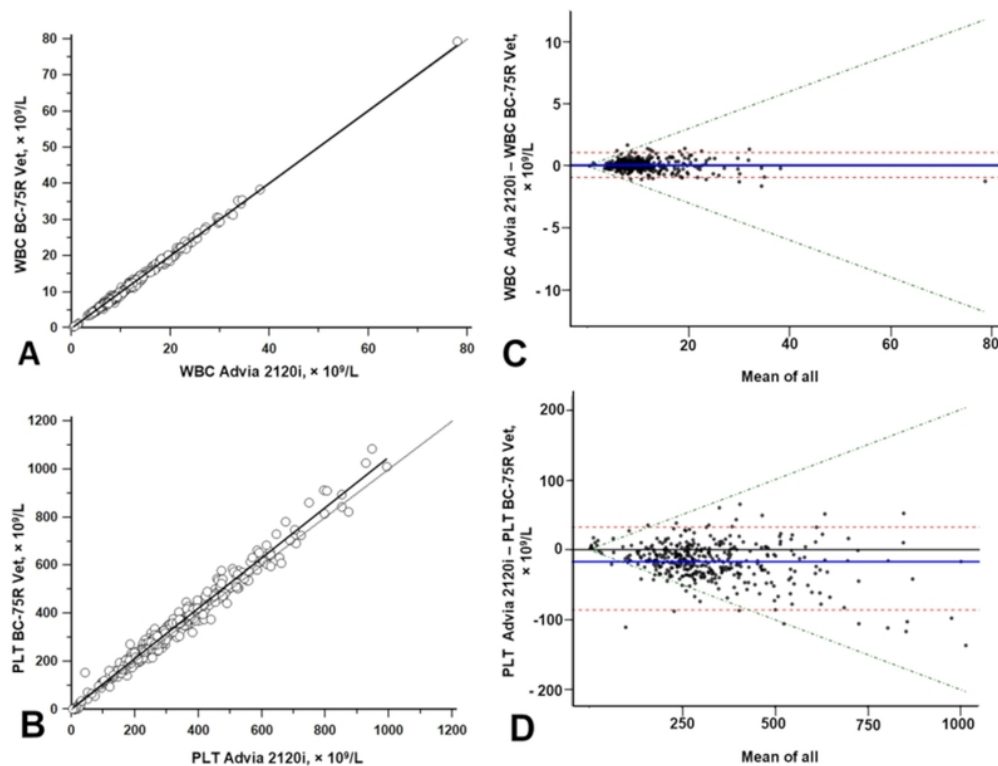


Figure 6. Agreement of WBC and platelet (PLT) counts obtained with the 2120i and the BC-75R Vet hematology analyzers for 411 canine samples. **A, B.** Passing-Bablok regression analysis. Dotted black line = identity line ($x = y$); solid black line = regression line. **C, D.** Bland-Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

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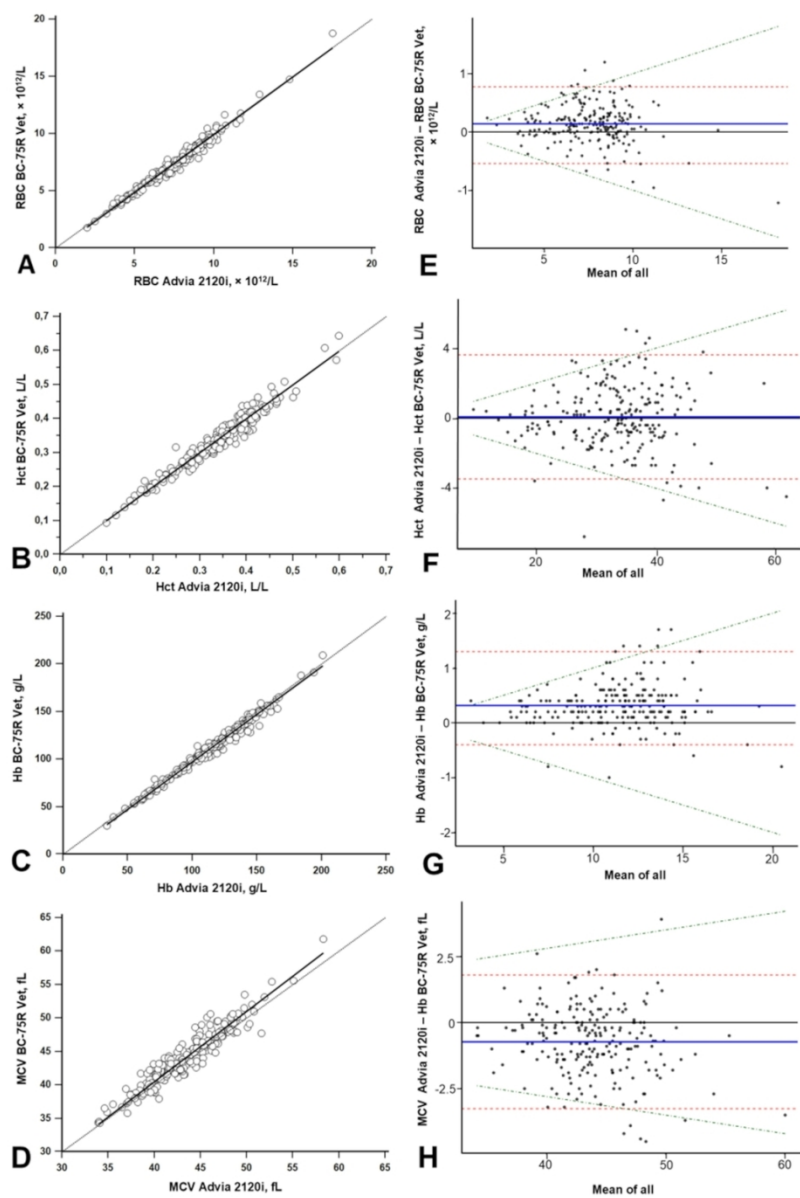


Figure 7. Agreement of RBC, Hct, Hb, and mean corpuscular volume (MCV) obtained with 2120i and BC-75R Vet hematology analyzers for 225 feline samples. **A–D.** Passing–Bablok regression analysis. Dotted black line = identity line ($x = y$); solid black line = regression line. **E–H.** Bland–Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

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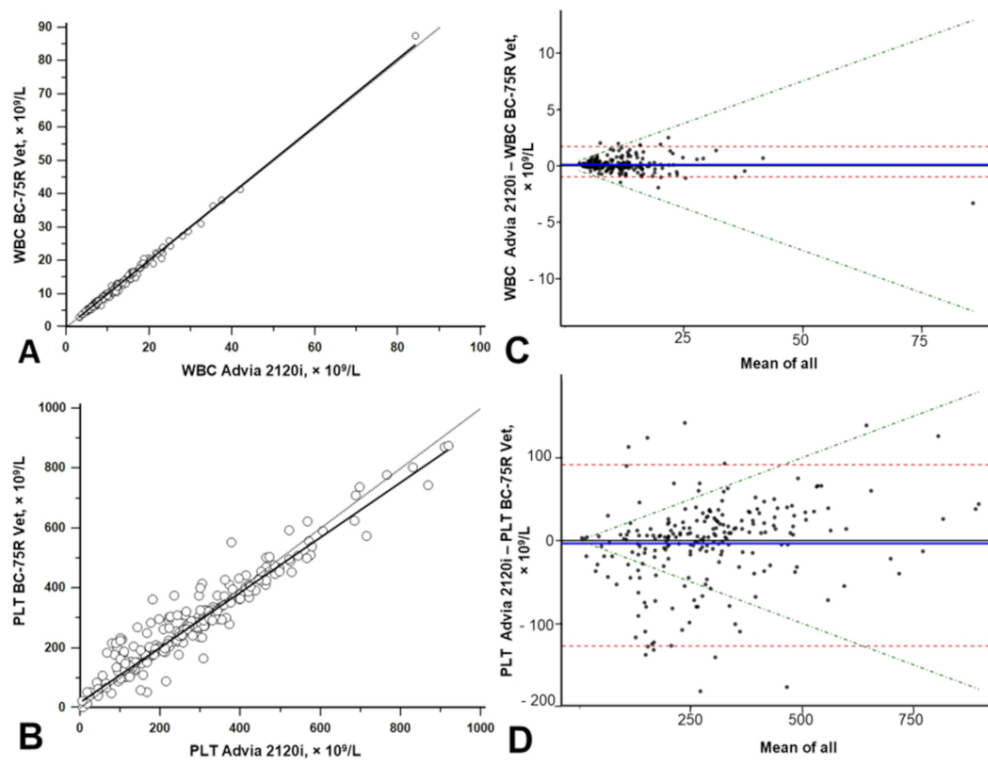


Figure 8. Agreement of WBC and platelet (PLT) counts obtained with 2120i and BC-75R Vet hematology analyzers for 225 feline samples. **A, B.** Passing-Bablok regression analysis. Dotted black line = identity line ($x = y$); solid black line = regression line. **C, D.** Bland-Altman plots of the absolute differences against the averages of results obtained by both analyzers. Solid blue line = mean absolute differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).

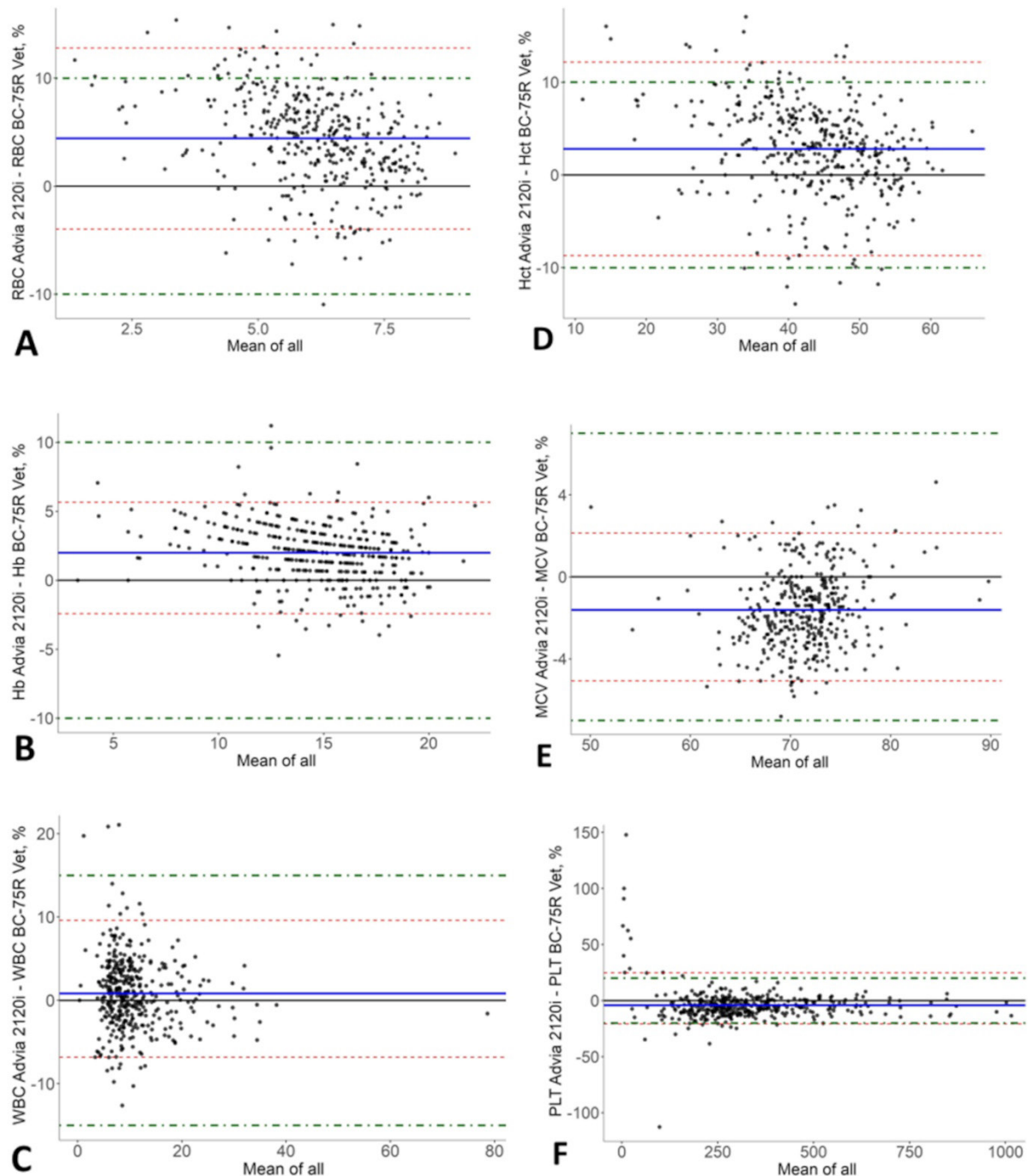
179x136mm (150 x 150 DPI)

JVDI: Supplemental material.

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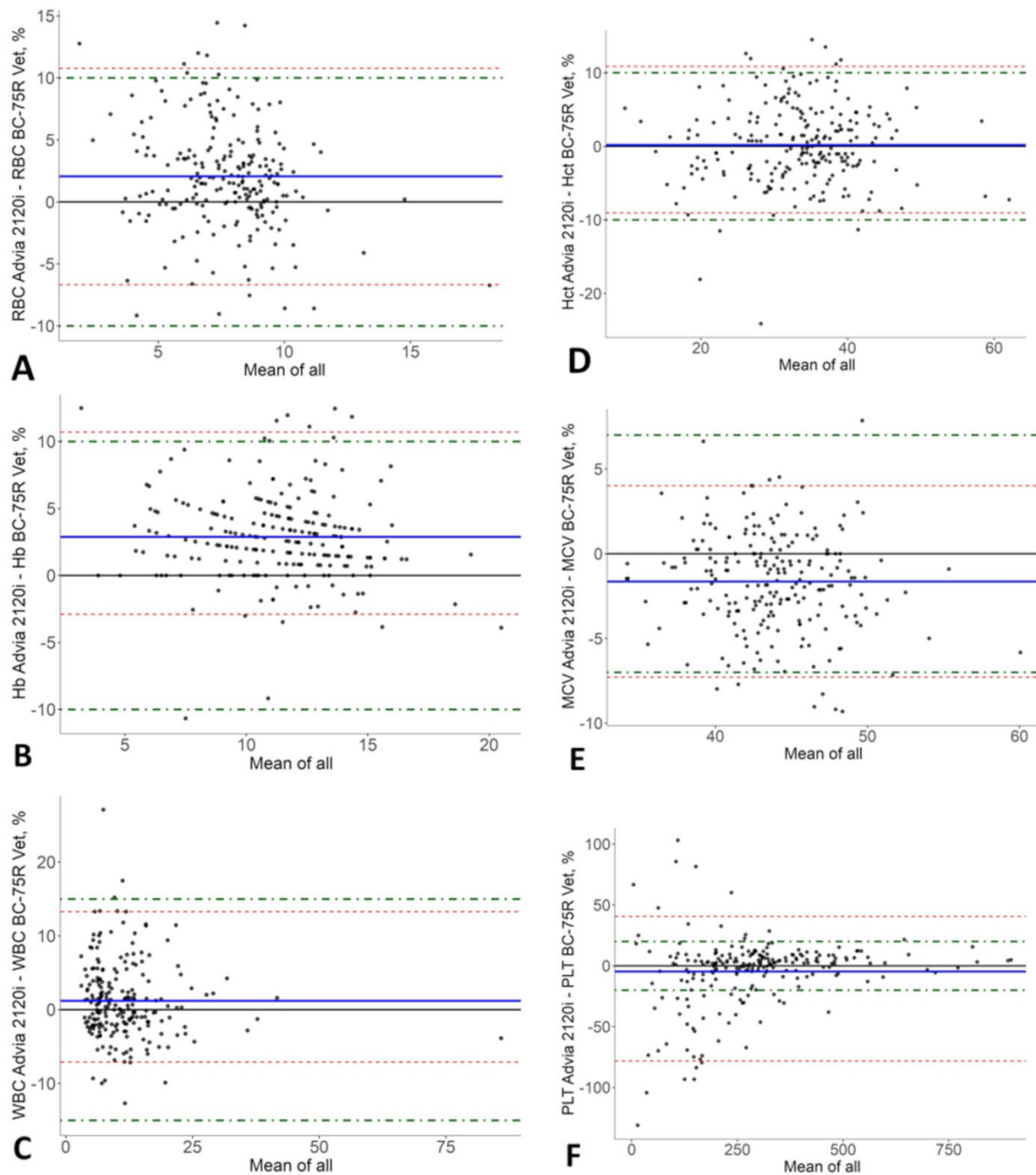
Supplemental Table 1. Descriptive data for QC analyses of the manufacturer-provided QC material, collected over 30-d using a single lot.

Variable	QC level											
	Low				Medium				High			
	Target $\bar{x} \pm$ acceptance limits	Observed $\bar{x}$	SD	CV%	Target $\bar{x} \pm$ acceptance limits	Observed $\bar{x}$	SD	CV%	Target $\bar{x} \pm$ acceptance limits	Observed $\bar{x}$	SD	CV%
RBC, $\times 10^{12}/L$	2.38 ± 0.18	2.32	0.02	1.11	4.29 ± 0.24	4.20	0.03	0.82	5.31 ± 0.3	5.16	0.04	0.86
Hct, L/L	0.21 ± 0.02	0.20	0.025	1.30	0.41 ± 0.03	0.40	0.035	0.89	0.53 ± 0.03	0.52	0.050	0.97
Hb, g/L	61 ± 0.4	60	0.05	0.91	124 ± 0.6	123	0.07	0.59	163	161	0.07	0.47
MCV, fL	86 ± 5	85	0.60	0.70	95 ± 5	94	0.71	0.76	101 ± 5	101	0.85	0.84
MCHC, g/L	298 ± 3	307	0.35	1.14	306 ± 3	311	0.24	0.78	305 ± 3	310	0.28	0.91
MCH, pg	25.6 ± 2.5	26.1	0.31	1.19	28.9 ± 2.5	29.3	0.25	0.88	30.7 ± 2.5	31.2	0.26	0.85
PLT-I, $\times 10^9/L$	53 ± 20	54	3.32	6.05	202 ± 45	193	5.88	3.03	402 ± 65	384	9.27	2.41
PLT-O, $\times 10^9/L$	124 ± 40	101	9.99	9.85	302 ± 60	276	14.50	5.25	507 ± 120	493	12.50	2.53
MPV, fL	13 ± 3	13	0.43	3.42	12 ± 3	11	0.18	1.64	12 ± 0.3	12	0.12	1.03
WBC, $\times 10^9/L$	3.51 ± 0.8	3.77	0.12	3.34	7.37 ± 1	7.50	0.15	2.06	21.17 ± 2.5	19.6	0.94	4.81
Neutrophils, $\times 10^9/L$	1.97 ± 0.5	2.12	0.08	4.17	3.58 ± 0.8	3.97	0.13	3.26	11.69 ± 2.08	13.15	0.39	3.01
Lymphocytes, $\times 10^9/L$	0.92 ± 0.4	0.95	0.04	4.64	2.71 ± 0.8	2.15	0.08	3.93	6.9 ± 1.67	3.7	0.87	23.45
Monocytes, $\times 10^9/L$	0.13 ± 0.17	0.11	0.01	13.07	0.38 ± 0.45	0.34	0.03	11.64	0.96 ± 1.56	0.67	0.24	36.78
Eosinophils, $\times 10^9/L$	0.44 ± 0.3	0.56	0.05	8.01	0.6 ± 0.54	0.95	0.09	9.71	1.35 ± 1.25	1.95	0.25	12.99
Reticulocytes, $\times 10^9/L$	78 ± 64	67	18.29	27.47	206 ± 99	200	14.31	7.17	179 ± 77	173	9.04	5.20



Supplemental Figure 1. Bland–Altman plots of the percentage differences against the averages of results obtained by the 2120i and the BC-75R Vet hematology analyzers in dogs.

Solid blue line = mean % differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).



Supplemental Figure 2. Bland–Altman plots of the percentage differences against the averages of results obtained by the 2120i and the BC-75R Vet hematology analyzers in cats. Solid blue line = mean % differences; dashed red lines = limits of agreement (LOAs); dot-dash green lines = total allowable error (TE_a).