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Review > Ann Lab Med. 2024 Sep 1;44(5):385-391. doi: 10.3343/alm.2024.0053. Epub 2024 Jun 5.

Next-Generation Patient-Based Real-Time Quality Control Models

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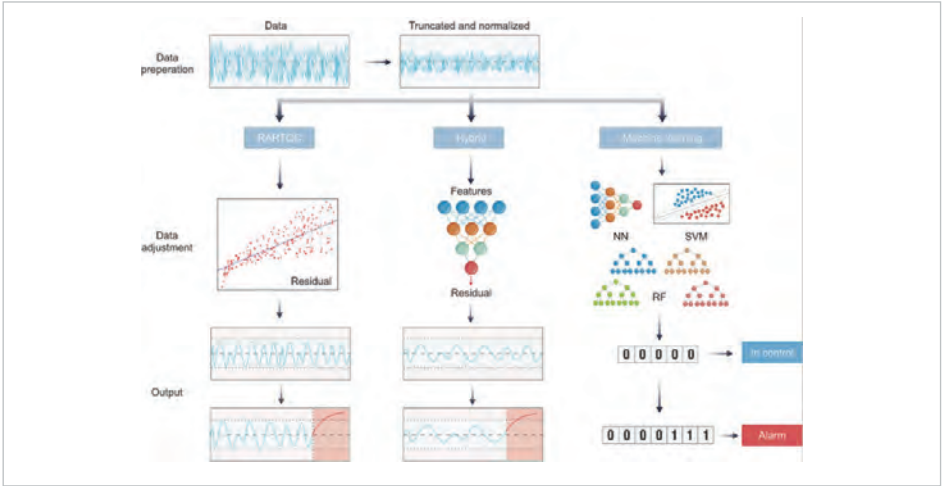
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Background: PBRTQC: improving quality control in the lab

Integrating patient-based real-time quality control (PBRTQC) protocols into healthcare settings enhances patient safety and reduces risks. The merging of machine learning (ML) and artificial intelligence with PBRTQC processes presents an opportunity to upgrade traditional methods and improve error detection in laboratory environments. This convergence represents an exciting frontier in healthcare management, promising to optimize performance and safety standards in clinical practices^[1].

[1] N Lorde, Si Mahapatra. Diagnostics (Basel). 2024 Aug 20;14(16):1808. doi: 10.3390/diagnostics14161808. Machine Learning for Patient-Based Real-Time Quality Control (PBRTQC), Analytical and Preanalytical Error Detection in Clinical Laboratory



Summary of three next-generation methods to improve PBRTQC performance.

Mindray's Patient-based real-time Quality Control (PBRTQC)^[2] method integrates patient data and Artificial Intelligence to enhance assay assessment. The PBRTQC algorithms, like Mindray's NN-PBRTQC, have evolved with computer science advancements, employing moving averages, regression-adjusted QC, neural networks, and anomaly detection. NN-PBRTQC efficiently predicts test values by incorporating patient-specific parameters through an ANN mapping model, while also reducing false alarms via an alarm filter. Hybrid models such as mNL-PBRTQC and PCRTQC further boost efficacy through machine learning and nonlinear regression. Mindray's NN-PBRTQC underscores the potential of AI-driven systems to revolutionize quality control in labs, improving precision and efficiency in healthcare.

[2] Y-F Liang, A Padoan, Clin Chem Lab Med. 2023 Nov 21;62(4):635-645. doi: 10.1515/cclm-2023-0964. Machine learning-based nonlinear regression-adjusted real-time quality control modeling: a multi-center study

DOI: 10.3343/alm.2024.0053



The MC-80 digital morphology analyzer takes digital form analysis to the next level, providing clearer images that capture more details of abnormalities and providing more clarity, intelligence, productivity in the digital morphology.

Hematology Literatures

MC-80 in Neoplastic & Reactive Cells

[Int J Lab Hematol. 2023 Dec;45\(6\):881-889. doi: 10.1111/ijlh.14160. Epub 2023 Aug 28.](#)

Artificial intelligence and the blood film: Performance of the MC-80 digital morphology analyzer in samples with neoplastic and reactive cell types

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Summary:

This comprehensive study on the MC-80 was conducted at two leading reference university hospitals by eminent Hematologists. It involved a dataset of 591 patients and evaluated the MC-80 performance in identification of neoplastic and reactive white blood cells (WBC).

MC-80 showed excellent sensitivity in identifying immature granulocytes (IG) (98.8%) and good efficiency and sensitivity in identifying reactive lymphocytes (95.2%, 93.6%). The negative predictive values of MC-80 were 99.2% for IG, 88.4% for neoplastic cells (lymphoblasts, myeloblasts, abnormal lymphocytes, abnormal promyelocytes and circulating plasma cells in multiple myeloma patients), 97.8% for reactive lymphocytes, and 96.9% for nucleated red blood cell (NRBC). Although the sensitivity and specificity of neoplastic cell classification was lower (83.8%, 86.1%), all samples were flagged by the digital morphology analyzer.

This study highlights the outstanding diagnostic performance of this artificial intelligence-based blood film analyzer for hematology patients with circulating abnormal cells. The authors appreciated the morphological harmonization of cells observed and displayed on the MC-80 screen and those seen down the microscope.

Download link: DOI: 10.1111/ijlh.14160

BC-6800Plus in Diagnostic Anticipation of Fungemia

> Int J Lab Hematol. 2024 May 6. doi: 10.1111/ijlh.14303. Online ahead of print.

Pseudo-NRBC in the Mindray BC-6800Plus analyzer:
A clue for diagnostic anticipation of fungemia.
Experimental and preliminary clinical reports

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Summary:

Abnormalities of the Mindray BC-6800Plus scattergram and generation of an NRBC flag can sometimes be related to circulating Candida fungi. This multi-center study sought to evaluate further this phenomenon.

A fungal bloodstream infection was simulated by adding various Candida types to 75 peripheral blood samples. In all experimental samples, the various Candida types caused pseudo-NRBC and morphological abnormalities of WNB and DIFF scattergrams. For clinical verification, 72 patients were recruited based on the presence of an evocative cluster in the WNB and DIFF cytograms. The microscopic review showed 39 out of 72 samples positive for NRBC. According to blood cultures, light microscopy revealed the presence of Candida was seen in the remaining 33 samples. Nine of these cases were not yet known to suffer from fungemia.

The presence of the NRBC flag and BC-6800Plus scattergram patterns may alert operators to the possible presence of fungemia in the peripheral blood.

Download link: DOI: 10.1111/ijlh.14303

BC-6800Plus for Myelodysplastic Syndromes Detection

> Diagnostics (Basel). 2024 Jun 21;14(13):1322. doi: 10.3390/diagnostics14131322.

Complete Blood Counts and Research Parameters in
the Detection of Myelodysplastic Syndromes

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Summary:

The diagnosis of Myelodysplastic syndromes (MDS) is challenging, especially for the distinction from the other non-neoplastic causes of cytopenia. Here, the complete blood count (CBC) and research parameters (RUO) from the analyzer BC-6800Plus were used to discriminate MDS-related cytopenia.

In the MDS group, the mean cell volume (MCV), percentage of macrocytic red cells (MAC), red cell distribution width (RDW) and immature platelets fraction (IPF) increased, compared to cytopenic and normal patients, while platelets, red and white cell counts, Neu X (neutrophil cytoplasmic complexity), Neu Y (nucleic acid content) and Neu Z (cell size) were lower ($p < 0.001$). Neu X, Neu Y, and Neu Z showed higher area under curve (AUC) for detecting MDS > 0.80 ; MAC, RDW and IPF $AUC > 0.76$.

Therefore, the BC-6800Plus CBC and RUO parameters can be used as a screen for early detection of dysplasia in MDS and in differential diagnosis of other causes of cytopenias.

Download link: DOI: 10.3390/diagnostics14131322

BC-6800Plus, SC-120 in Myelodysplastic Neoplasms Diagnosis

> [Int J Lab Hematol.](#) 2023 Aug;45(4):522-527. doi: 10.1111/ijlh.14057. Epub 2023 Mar 15.

Combination of NeuX and NeuZ can predict neutrophil dysplasia features of myelodysplastic neoplasms in peripheral blood

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Summary:

The assessment of neutrophil dysplasia (ND) features in peripheral blood is very helpful for the early screening and diagnosis of myelodysplastic neoplasms (MDS).

In this study, Mindray BC-6800Plus automatic hematology analyzer and Mindray SC-120 Automatic Slide Maker were used to analyze and reveal the significance of cell population data (CPD) neutrophil (Neu) X, NeuY and NeuZ in assessment of ND. The median values of NeuX and NeuZ in MDS with granulocyte dysplasia group were significantly lower than those in MDS without granulocyte dysplasia group and control group ($p < 0.001$), and they were positively correlated ($r = 0.878$, $p < 0.001$).

The combination of Mindray BC-6800Plus CPD parameters NeuX and NeuZ can predict ND features of MDS in peripheral blood. Therefore the screening for early detection of ND cases is possible with the BC-6800Plus and alerts operators to the possible presence of ND cells.

Download link: DOI: 10.1111/ijlh.14057

BC-6800Plus in Establishing Pediatric Reference Intervals

> [Int J Lab Hematol.](#) 2023 Aug;45(4):469-480. doi: 10.1111/ijlh.14068. Epub 2023 Mar 29.

Comprehensive pediatric reference intervals for 79 hematology markers in the CALIPER cohort of healthy children and adolescents using the Mindray BC-6800Plus system

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Summary:

Hematological parameters vary significantly throughout growth and development due to physiological processes such as fetal-to-adult erythropoiesis and puberty. pediatric age- and sex-specific reference intervals (RIs) are thus essential for appropriate clinical decision-making.

This study aimed to establish RIs for both common and novel (CPD) hematology parameters on the Mindray BC-6800Plus system. A healthy cohort of Canadian children and adolescents (from 30 days to 18 years) was used to generate hematology RI data on 79 parameters. Dynamic reference value distributions were observed for several hematology parameters, including erythrocytes, leukocytes, platelets, reticulocytes, and research-use only markers. Age and sex also have impact on the value distributions.

The data emphasize the complex biological patterns of hematology parameters in childhood, particularly at the onset of puberty, and support the need for age- and sex-specific RIs for clinical interpretation. This important hematology study can be used as a reference for assessment of pediatrics and adolescents' samples on Mindray analyzers.

Download link: DOI: 10.1111/ijlh.14068

BC-720 ESR-Clinical Detection Efficiency

> *Int J Lab Hematol.* 2023 Aug;45(4):449-459. doi: 10.1111/ijlh.14044. Epub 2023 Mar 13.

Clinical application of a new method for determination of the erythrocyte sedimentation rate using the BC-720 automated hematology analyzer

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Summary:

The study evaluated the performance of a new, rapid ESR method (Easy-W ESR) which is part of the Mindray BC-720 automated hematology analyzer. It compared the BC-720 analyzer ESR results with the Westergren method (gold standard), assessing various parameters like repeatability, carryover, sample stability, and clinical applicability.

The results showed good correlation, low carryover, and acceptable repeatability between the two methods. For rheumatology patients, the BC-720 analyzer showed excellent correlation with the Westergren method ($Y = 1.021X - 1.941$, $r = 0.9467$, $n = 149$). For orthopedic patients, the BC-720 analyzer also showed excellent correlation with the Westergren method ($Y = 1.037X + 0.981$, $r = 0.978$, $n = 97$).

In conclusion, the new ESR method on the BC-720 analyzer provides clinically comparable results to the gold standard Westergren method. The BC-720 ESR result is accurate, saves time, is low cost and is generated at the same time as the CBC from the EDTA samples.

Download link: DOI: 10.1111/ijlh.14044

BC-6800Plus Parameters for Sepsis Detection

> *Clin Chem Lab Med.* 2022 Nov 11;61(2):356-365. doi: 10.1515/cclm-2022-0713. Print 2023 Jan 27.

Diagnostic performance of machine learning models using cell population data for the detection of sepsis: a comparative study

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Summary:

This multi discipline study used the Multi-layer Perceptron (MLP) process on a cohort of 698 emergency department patients and aimed to compare various machine learning and artificial intelligence algorithms to detect sepsis. Mindray BC-6800Plus data, including Cell Population Data (CPD) were evaluated for the sepsis study.

The MLP is an artificial neural network composed of three AI layers. The first is the input layer, the intermediates are called hidden layers, and finally the output layer contains the results of the aggregate data inputs computation. The neurons in the MLP are trained with the back propagation learning algorithm. CPD parameters LYM-Z, LYM-X, and NLR were the most important for sepsis prediction, with LYM-Z and NEU-Z negatively related to sepsis presence. The MLP for sepsis achieved the following results: accuracy of 0.86, AUC of 0.95, sensitivity of 0.93 and specificity of 0.81 (threshold of 0.34).

Mindray leads the way in AI algorithms and early disease detection based on CPD data. These CPD data are available on all samples and provide clinicians with early indicators to the presence of sepsis.

Download link: DOI: 10.1515/cclm-2022-0713

BC-6800Plus in Diagnosis of Malaria

Case Reports > Int J Lab Hematol. 2024 Apr;46(2):209-211. doi: 10.1111/ijlh.14172.
Epub 2023 Sep 13.

The role of infected red blood cells flag (InR) of Mindray BC 6800 plus in malaria diagnosis

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Summary:

An 8-year-old patient with symptoms including fever, headache, and vomiting presented to Novara's Hospital in Italy. The patient had traveled to Nigeria 18 months prior. The Mindray BC-6800Plus was used to generate the CBC and InR flags.

The Mindray BC-6800Plus analyzer generated a CBC result which included the InR (Infected RBC) flag suggesting the possible presence of Malarial parasites. Further diagnostic tests including a rapid malaria test and peripheral blood smear analysis confirmed the presence of small number of malaria parasites, specifically those of Plasmodium Malariae.

The Mindray BC-6800Plus analyzer demonstrated its effectiveness in screening for the presence of malarial parasites. Even with low percentages of parasitemia, as in this case, operators are alerted to the possible presence of Malaria and can therefore instigate further confirmatory studies. This study further emphasizes the value of the Mindray BC-6800Plus analyzer as an excellent screen for the presence of even small numbers of Malarial Parasites.

Download link: DOI: 10.1111/ijlh.14172

BC-6800Plus Clinical Value of RDW in Prostate Cancer

> J Inflamm Res. 2021 Nov 23;14:6115-6127. doi: 10.2147/JIR.S342272. eCollection 2021.

Association Between Pre-Treatment and Post-Treatment 3-Month Red Cell Distribution Width with Three-Year Prognosis of Prostate Cancer

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Summary:

This study investigated the relationship between pre-/post-treatment RDW levels and changes in RDW with 3-year prognosis in prostate cancer patients.

The levels of pre-treatment ($14.05\% \pm 1.63\%$ vs $18.18\% \pm 2.31\%$) and post treatment ($13.37 \pm 1.60\%$ vs $19.10 \pm 2.48\%$) RDW levels were significantly higher in the death group compared with those in the survival group ($p < 0.001$). Persistent increases in RDW were significantly associated with decreased overall and cancer-specific survival.

Measurement of RDW levels and changes before and after treatment with BC-6800Plus hematology analyzer predicted 3-year prognosis in patients with prostate cancer. This study indicates that measurement of the BC-6800Plus RDW is a potential prognostic marker in patients with Prostate Cancer.

Download link: DOI: 10.2147/JIR.S342272

BC-6200 vs Siemens ADVIA 2120i

Comparative Study > Int J Lab Hematol. 2021 Jun;43(3):395-402. doi: 10.1111/ijlh.13418. Epub 2020 Dec 3.

Evaluation and comparison of the new Mindray BC-6200 hematology analyzer with ADVIA 2120i

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Summary:

The study evaluated the BC-6200 hematology analyzer's performance by comparing it with the ADVIA 2120i analyzer using 390 whole blood samples. Assessments included carryover effect, precision, linearity, and sensitivity for detecting abnormal cells, with flagging results validated against microscopic evaluation.

The BC-6200 demonstrated high correlation with ADVIA 2120i for most parameters, and superior correlation with microscopic for NRBC compared to ADVIA 2120i. Furthermore, BC-6200 efficiently flagged blasts (80.4%), immature granulocytes (80.5%), and atypical lymphocytes (69.0%).

The BC-6200 exhibits high precision and good correlation with ADVIA 2120i for most morphology and 5-diff parameters, underscoring its reliability and suitability for clinical use.

Download link: DOI: 10.1111/ijlh.13418

WBC Classification Performance of MC-80

> Int J Lab Hematol. 2023 Oct;45(5):691-699. doi: 10.1111/ijlh.14119. Epub 2023 Jun 20.

White blood cell differentials performance of a new automated digital cell morphology analyzer: Mindray MC-80

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Summary:

This prospective study on the MC-80 analyzed a dataset of 934 samples (100 normal and 834 abnormal) for its ability to accurately identify normal and abnormal white blood cells (WBC). The MC-80 was evaluated for sensitivity and specificity of each WBC type using pre-classification and post-classification criteria.

The cell identification performance was analyzed on 194,009 cells. Overall, the specificity of WBC identification was higher than 95% for all cell classes, and sensitivity greater than 95% for most cell classes. Compared to manual counting, MC-80 yields a very good correlation ($r > 0.90$) and minimal differences for most cell classes. The highest correlation was found in nucleated red blood cells (NRBC) ($r = 0.99$).

The performance of the Mindray MC-80 for WBC differentials is reliable and is acceptable even in abnormal samples. However, the sensitivity is less than 95% for certain rare abnormal cell types, so the user should be aware of this limitation.

Download link: DOI: 10.1111/ijlh.14119

MC-80 vs CellaVision DM9600

> Int J Lab Hematol. 2024 Feb;46(1):72-82. doi: 10.1111/ijlh.14178. Epub 2023 Sep 25.

Performance of the new MC-80 automated digital cell morphology analyser in detection of normal and abnormal blood cells: Comparison with the CellaVision DM9600

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Summary:

This study on the Mindray MC-80 was conducted at a highly respected tertiary reference center in Barcelona Spain. A dataset of 445 samples (194 normal and 251 abnormal samples) were analyzed. The abnormal samples included 100 with acute leukemia and another 97 with various hematological neoplasms and circulating immature cells. The objective of this study was to compare the MC-80 performance with the CellaVision® DM9600 and the reference WBC manual microscopic count.

Compared with the microscope, the MC-80 showed strong correlation and concordance for all types of leucocytes, including immature granulocytes (IG) (r values between 0.91 and 1.0) in both pre- and post-classification modes. The MC-80 showed the highest correlation in the identification and percentage of blasts using pre- and post-classification modes (0.954, 0.969).

MC-80 demonstrated high performance for WBC differential in both normal samples and patients with hematological diseases including those with blasts in the peripheral blood.

Download link: DOI: 10.1111/ijlh.14178

BC-6800Plus and MC-80 Enables Accurate Platelet Count

> Ann Lab Med. 2024 Nov 1;44(6):478-486. doi: 10.3343/alm.2023.0460. Epub 2024 Apr 4.

Integration of an MC-80 Digital Image Analyzer With an Automated BC-6800Plus Hematology Analyzer Enables Accurate Platelet Counting in Samples With EDTA-Induced Pseudothrombocytopenia

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Summary:

EDTA-induced pseudothrombocytopenia (PTCP) requires significant laboratory resources to obtain accurate results including recollection into citrate anticoagulant. This study evaluated the unique optical platelet deaggregation function and platelet-clump flagging of the BC-6800Plus hematology analyzer integrated with digital image analyzer MC-80 in EDTA-induced PTCP.

A dataset of 132 whole blood samples including 43 EDTA samples with platelet clumping were analyzed. The DxH 900 PLT-I and BC-6800Plus PLT-I (impedance) results demonstrated reasonable correlation (r=0.711) for the EDTA samples but a moderate correlation with the BC-6800Plus PLT-O (optical) results (r=0.506 and 0.545, respectively). The BC-6800Plus PLT-O results were consistent with the sodium citrate platelet counts in PTCP samples. Integrating the MC-80 results, the sensitivity of BC-6800Plus for platelet-clump flagging improved from 0.72 to 0.89 (standard mode) or 1.0 (PLT-Pro mode).

Integration of the unique BC-6800Plus PLT-O Optical count with MC-80 improves dramatically the accuracy of platelet counting in EDTA related PTCP. It also improves laboratory productivity and reduces the need for recollection in many patients.

Download link: DOI: 10.3343/alm.2023.0460

BC-700 PLT-H for Accurate Platelet Counting

> *Platelets*. 2023 Dec;34(1):2287064. doi: 10.1080/09537104.2023.2287064. Epub 2023 Nov 30.

Performance evaluation of PLT-H (hybrid-channel platelet) under various interferences and application studies for platelet transfusion decisions

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Summary:

The hybrid-channel platelet counting method (PLT-H) is a new platelet counting technique developed by Mindray. This study evaluated the accuracy and reliability of PLT-H in various clinical situations.

In the absence of interference, there was a strong correlation between PLT-H and the reference method Immunoplatelet Reference Method (PLT-IRM) ($r = 0.993$). Under various interference conditions, the correlation between PLT-H and the PLT-IRM was between 0.963 and 0.992. The performance of PLT-H against interference did not change significantly with increasing levels of small RBCs, large PLTs, and RBC fragments. In low-value samples ($PLT < 100 \times 10^9/L$), the CV for PLT-H was less than 7.6%, with or without interference. In addition, there was a high agreement between PLT-H and PLT-IRM ($ICC = 0.972$).

PLT-H is a novel, accurate method for platelet counting offering higher accuracy even in the presence of interferents. The results indicate that PLT-H can reliably be used by clinicians for PLT transfusion decision-making without incurring additional costs.

Download link: DOI: 10.1080/09537104.2023.2287064

BC-780 for Platelet Interference Samples

> *Clin Chem Lab Med*. 2023 Oct 20;62(4):690-697. doi: 10.1515/cclm-2023-1000. Print 2024 Mar 25.

Performance evaluation of a novel platelet count parameter, hybrid platelet count, on the BC-780 automated hematology analyzer

Eakachai Prompetchara ¹, Chalisa Parnsamut ¹, Angkana Chirapanuruk ², Chutitorn Ketloy ¹

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Summary:

This study aimed to evaluate the performance of the three Mindray BC-780 platelet counting methods in thrombocytopenic samples and those where platelet interferences existed. The three methods included the novel, new platelet counting, hybrid (PLT-H) method, the Impedance (PLT-I) and optical (PLT-O) were correlated against the Immunoplatelet Reference Method (IRM) in those specific important conditions where platelet counts must be accurate for clinical decision making.

All three platelet counting methods exhibited high comparability with the IRM (the lowest correlation, $r = 0.916$). Interestingly, the comparability of PLT-H ($r = 0.928-0.986$) with the IRM was better than that of PLT-I ($r = 0.916-0.979$).

Overall, PLT-H exhibits better reproducibility, correlates well with the PLT-O and demonstrates excellent performance in generation of accurate platelet counts in the presence of small RBC, giant platelets good anti-interference ability. Thus, PLT-H counting is recommended as a zero-cost alternative for accurate platelet counting in thrombocytopenic samples where interferences may exist.

Download link: DOI: 10.1515/cclm-2023-1000

BC-780 Rapid ESR vs Westergren Method

> Clin Chem Lab Med. 2023 Sep 22;62(2):303-311. doi: 10.1515/ccim-2023-0499. Print 2024 Jan 26.

Performance evaluation of alternate ESR measurement method using BC-780 automated hematology analyzer: a comparison study with the Westergren reference method

Eakachai Prompetchara ¹, Chalisa Parnsamut ¹, Nathawit Wangviwat ², Patrawadee Pitakpolrat ¹, Kwanlada Chaiwong ², Orakarn Limpompukdee ¹, Surapat Tanticharoenkarn ², Chutitorn Ketloy ¹

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- 2 Division of Laboratory Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand.

Summary:

This study evaluated the Mindray BC-780 analyzer's analytical performance looking specifically at the rapid ESR measurement. ESR precision, carryover, stability, and performance in the presence of potential interferences were assessed.

Results from this study showed the BC-780 met precision and carryover claims, and the ESR result was stable for 24 hours if the sample was stored at 2-8°C or for 8 hours at RT. After 24 hours storage a decrease in ESR result was observed. Hemolysis/lipemia samples showed a significant increase in the ESR result. Comparison with Westergren ESR showed a positive bias, mean bias 3.12 mm, mostly <5 mm – however this bias fall within acceptable criteria.

BC-780 analyzer performed well, comparable to the gold standard Westergren reference method in the majority of samples with a small acceptable bias. Further validation studies are required to establish at what levels hemolysis/lipemia interferences affect the BC-780 ESR.

Download link: DOI: 10.1515/ccim-2023-0499

BC-720 Reference Range and Performance of ESR

> Ann Transl Med. 2022 Sep;10(17):922. doi: 10.21037/atm-22-3486.

Performance evaluation of the BC-720 auto hematology analyzer and establishment of the reference intervals of erythrocyte sedimentation rate in healthy adults

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- 2 Department of Laboratory Medicine, Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China.
- 3 Department of Laboratory Medicine, The First Affiliated Hospital of Soochow University, Suzhou, China.

Summary:

This multi-center study evaluated the new BC-720 automated hematology analyzer's ESR parameter by comparing it with the gold standard Westergren method and a modified Westergren (LBY-XC40B) methods. Repeatability, carryover, and reference intervals (RI) were determined.

BC-720 ESR correlated well with Westergren (r = 0.957), had good repeatability (SD ≤ 1 mm/h, CV ≤ 5%), and had low carryover (< 1%). Reference intervals were up to 15 mm/h for men and up to 24 mm/h for women.

The Mindray BC-720 ESR showed high accuracy and good repeatability, which provided a faster, safer, and more reliable method to measure ESR. The reference intervals for BC-720 ESR could guide better clinical decisions for the laboratories utilizing this new method.

Download link: DOI: 10.21037/atm-22-3486

BC-6800Plus vs XN-9000 Platelet Counts

> *Diagnostics (Basel)*. 2021 Dec 29;12(1):68. doi: 10.3390/diagnostics12010068.

Performance of Platelet Counting in Thrombocytopenic Samples: Comparison between Mindray BC-6800Plus and Sysmex XN-9000

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Summary:

The performance of platelet counting in thrombocytopenic samples is crucial for transfusion decisions. This study compared PLT counting and reproducibility in a dataset of 516 samples on the Mindray BC-6800Plus and the Sysmex XN-9000 hematology analyzers.

This large study from a highly respected Korean Laboratory showed moderate to very high correlation between the BC-6800Plus PLT-I and Sysmex XN PLT-I. The BC-6800Plus PLT-O vs. XN PLT-F showed a high to very high correlation. Both comparisons demonstrated excellent agreement ($\kappa = 0.93$ and 0.94).

The authors concluded that the BC-6800Plus would be a reliable option for PLT counting in thrombocytopenic samples with good reproducibility. Inference is BC-6800Plus can be used reliably to inform clinicians about Platelet Transfusion decision making.

Download link: DOI: 10.3390/diagnostics12010068

BC-6800Plus Optical Platelet (PLT-O)

> *Int J Lab Hematol*. 2022 Apr;44(2):281-287. doi: 10.1111/ijlh.13753. Epub 2021 Dec 6.

Performance evaluation of the new platelet measurement channel on the BC-6800 Plus automated hematology analyzer

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- ² Department of Geriatrics, Ruijin Hospital affiliated to Shanghai Jiaotong University School of Medicine, Shanghai, China.

Summary:

This study evaluated the BC-6800Plus analyzer's new optical platelet measurement channel (PLT-O 8 $\times$) performance, comparing it to flow cytometry and PLT-I (Impedance). The patient dataset included various, difficult specimen types including low-PLT, samples with abnormal RBCs, and those with EDTA-dependent PLT aggregation present.

The BC-6800Plus PLT-O 8 $\times$ and PLT-I both exhibited high comparability with the reference flow cytometry method ($r = 0.97$). In EDTA-anticoagulated blood specimens from 20 patients with EDTA-dependent PLT aggregation, the results of PLT-O were significantly higher than those for PLT-I using samples from the same tubes ($P < 0.001$). However, the PLT counts were similar between these two methods for sodium citrate-anticoagulated blood specimens ($P = 0.263$) indicating PLT-O was suitable for accurate platelet counting of EDTA-dependent PLT aggregation samples.

The BC-6800Plus's PLT-O 8 $\times$ demonstrated superior technical performance and accuracy over PLT-I, especially in challenging samples, indicating its suitability for clinical use.

Download link: DOI: 10.1111/ijlh.13753



The EU 8600/EU 8600 GT fully automated urinalysis line has advanced features including RBC phase parameters, clear images and a modular design to provide accurate results, and a thorough review and verification process to quickly and accurately identify the source of hematuria.



Urinalysis Literature

EH-2090 in Urine Analysis

> [Transl Androl Urol.](#) 2024 Feb 29;13(2):218-229. doi: 10.21037/tau-23-626. Epub 2024 Feb 20.

Performance analysis of urine formed element analyzer EH-2090 was found to have good accuracy in detecting RBCs and WBCs when compared to manual microscopic

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Affiliations

Affiliations

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Contributed equally.

Summary:

EH-2090 is Mindray' s new-generation fully automated urine formed element analyzer (referred to as EH-2090). Currently, there are no studies on EH-2090, so this study sought to evaluate the analytical and clinical performance of this urinalysis analyzer. Manual microscopy methods were used as the reference.

The results demonstrate that the EH-2090 has good analytical and clinical performance. There was a good correlation between the counting accuracy of RBCs ($r = 0.965$, $P < 0.0001$) and WBCs ($r = 0.894$, $P < 0.0001$) by the EH-2090 and the Fuchs-Rosenthal method.

Thus, the RBC and WBC counting accuracy of EH-2090 correlates well with the quantitative reference method of microscopy. Moreover, EH-2090 provides images of the formed components of urine and through automation significantly improves productivity, turnaround times for urinalysis and reduces the workload of the laboratory technician.

Download link: DOI: 10.21037/tau-23-626

UA-5600 in Urine Analysis

> [Transl Androl Urol.](#) 2024 Jun 30;13(6):1024-1036. doi: 10.21037/tau-24-189. Epub 2024 Jun 27.

Performance evaluation and clinical application of the UA-5600 automatic dry chemistry urine analyzer in renal diseases

Yin Liu ^{# 1}, Xiaohe Zheng ^{# 1}, Dong Wang ¹, Fei Fang ¹, Yao Chen ¹, Mengzhi Hong ¹, Jiali Wu ¹, Chi Zhang ¹, Yangyang Qiao ¹, Iyare Izevbaye ², Shihong Zhang ¹

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- 2 Department of Pathology and Laboratory Medicine, Emory University School of Medicine, Grady Health System, Atlanta, GA, USA.

Summary:

BLD (blood), LEU (leukocyte), PRO (protein) and GLU (glucose) are the four most important parameters in urine testing, and the accuracy of laboratory test results is a key concern for clinicians, so it is essential to verify the accuracy of their results.

This study evaluated the analytical and clinical performance of Mindray's automatic urine dry chemistry analyzer, the UA-5600. It had an 89.55% concordance rate for BLD and a 91.04% concordance rate for LEU compared to the EH-2090 analyzer. When benchmarked against the Mindray BS-2800M, the concordance rates for PRO and GLU were 94.14% and 95.20%, respectively.

In conclusion, the Mindray UA-5600 demonstrates robust detection abilities for both BLD and LEU, and its results for PRO and GLU align closely with those obtained from the Mindray chemistry analyzer. Additionally, the output parameters could be used for machine learning-based disease screening system.

Download link: DOI: 10.21037/tau-24-189



BriCyte MX is a new addition to Mindray's flow cytometry family, featuring a 3-laser configuration for expanded applications and multi-layer automation for increased efficiency. With its flexible software and suitability for a broad range of test panels, the BriCyte MX unlocks efficient cytometry with its multi-colored lasers.

Flow Cytometry Literature



BriCyte E6 for T-spot and Active Tuberculosis

> BMC Infect Dis. 2019 Jul 29;19(1):673. doi: 10.1186/s12879-019-4310-y.

Quantitative investigation of factors relevant to the T cell spot test for tuberculosis infection in active tuberculosis

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- 3 Department of Infectious Diseases, Ankang Central Hospital, 85 South Jinzhou Road, Ankang, 725000, Shaanxi Province, China. hbsyemcl@163.com.

Summary:

The purpose of this study was to investigate the factors affecting quantified spot-forming cells (SFCs) using the Mindray BriCyte E6 system for early secreted antigenic target 6 kDa (ESAT-6) or culture filtrate protein 10 kDa (CFP-10) in patients with active tuberculosis. The results showed that the SFCs to ESAT-6 regression model had statistical significance ($P < 0.001$) and that previous treatment and CD4+ and platelet counts were its independent risk factors (all $P < 0.05$).

In T-SPOT.TB-assisted diagnosis of patients with active tuberculosis, CD4+ and CD8+ might lead to an increase in the false negative rate of the T-SPOT.TB

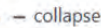
Download link: DOI: 10.1186/s12879-019-4310-y

BriCyte E6 for Discovery in Autoimmune Studies

> Nat Immunol. 2022 Nov;23(11):1644-1652. doi: 10.1038/s41590-022-01325-9. Epub 2022 Oct 21.

CMTM4 is a subunit of the IL-17 receptor and mediates autoimmune pathology

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- 3 Czech Centre for Phenogenomics and Laboratory of Transgenic Models of Diseases, Institute of Molecular Genetics of the Czech Academy of Sciences, Vestec, Czech Republic.

Summary:

This study published in Nature Immunology used the Mindray BriCyte E6 to identify CMTM4 as an essential component of IL-17R and a potential therapeutic target for treating IL-17-mediated autoimmune diseases.

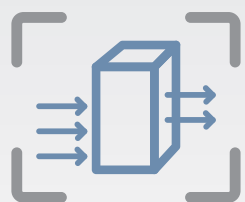
CMTM4 is constitutively associated with IL-17RC; CMTM4 mediates IL-17RC glycosylation and localization; Glycosylation regulates IL-17RC plasma membrane trafficking; CMTM4 is required for IL-17A-induced signaling responses; CMTM4 regulates IL-17R-mediated inflammation in vivo.

CMTM4 assembled together with IL-17RC and IL-17RA to form the ligand-engaged IL-17RSC and was required for the cellular responses to IL-17. The Mindray platform played an important role in this discovery which was published in the prestigious Nature Immunology journal.

Download link: DOI: 10.1038/s41590-022-01325-9



The BS-2000M is a floor-standing, modular, discrete and random access clinical chemistry analyzer offering constant throughput of 2000 tests per hour with Sample Delivery Module.



Biochemistry Literature

BS-2800M for Hydrothorax and Ascites Samples

> J Thorac Dis. 2024 May 31;16(5):3350-3360. doi: 10.21037/jtd-24-345, Epub 2024 May 20.

Performance verification of a biochemical detection system for hydrothorax and ascites and clinical diagnostic accuracy evaluation of exudate and tuberculous effusion

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- 3 Department of Laboratory Medicine, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, China.

Summary:

This multi-center study assessed the biochemical hydrothorax and ascites detection system on the Mindray BS-2800M fully automatic biochemical analyzer.

The study evaluated the clinical diagnostic accuracy of Mindray biochemical reagents in diagnosing pleural effusion and ascites. Results indicated that these biochemical reagents met quality control requirements, the repeatability coefficient of variation (%) of LDH, TP, Glu, and ADA were all less than 1%, The limits of blank of LDH, TP, Glu, and ADA were 0.33 U/L, 0.45 g/L, 0.00 mmol/L, and 0.04 U/L, respectively; the limits of detection were 1.57 U/L, 1.85 g/L, 0.05 mmol/L, and 0.12 U/L, respectively.

LDH, TP, Glu, and ADA tests on the Mindray BS-2800 analyzer help differentiate exudates and transudates in hydrothorax and ascites, with ADA aiding in distinguishing tuberculous from non-tuberculous effusions.

Download link: DOI: 10.21037/jtd-24-345

BS-2000M vs Roche Cobas 8000

> J Med Biochem. 2022 Jul 29;41(3):306-315. doi: 10.5937/jomb0-34328.

Performance evaluation between two automated biochemical analyzer systems: Roche Cobas 8000 and Mindray BS2000M

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¹ First Affiliated Hospital of Guangxi Medical University, Department of Clinical Laboratory, China.

Summary:

This study looked at the crucial role accurate biomarker values make in in clinical decisions. Biochemistry biomarkers CK, LDH-1, RBP, Cys-C, IgA, IgM, and IgG results were compared between the Roche Cobas 8000 and Mindray BS2000M analyzers.

There were significant differences in the average bias of all items between the two analyzers ($P < 0.001$). Passing-Bablok regression analysis showed no systematic error for CK, LDH-1, Cys-C, and IgG, while IgM exhibited consistent bias measurements. Strong correlations ($r > 0.91$) were observed for most items except IgA. Bland-Altman analysis indicated data point variations in over 95% of cases, except for CK, LDH-1, and IgA, emphasizing the need for assessing analyzer performance in clinical settings.

It can be considered that the Roche Cobas 8000 and Mindray BS2000M analyzers. have good correlation and reproducibility for CK, LDH-1, RBP, Cys-C, IgM, and IgG, biomarkers. Results indicate both analyzers generate similar results for the aforementioned biomarkers and are interchangeable and can replace each other.

Download link: DOI: 10.5937/jomb0-34328

SAL 8000 - An Integrated Analyzer

> Clin Lab. 2019 Jul 1;65(7). doi: 10.7754/Clin.Lab.2019.181228.

Performance Evaluation of Mindray SAL 8000: a New Integrated Clinical Chemistry and Immunoassay Analyzer System

Jie Yang, Maocheng Li, Hanyun Zhang, Peng Zhang, Lifei Zhao, Deyu Zeng, Ling Li, Huihui Fan, Fangyin Zeng

Summary:

The Mindray SAL 8000 is an integrated serum analyzer for photometric, electrochemical, and immunological assays. The technical, analytical, and workflow performance of the system were evaluated in this study.

The repeatability and within-laboratory coefficients of variation (CVs) ranged between 0.22% and 4.23% for routine chemistry and between 1.05% and 6.89% for immunochemistry assays. For the dataset of 1,220 samples, 25%, 54%, 63%, 79%, 91%, and 100% samples completed analysis in 16.3 minutes, 30 minutes, 60 minutes, 120 minutes, 180 minutes, and 320 minutes, respectively. The system demonstrated acceptable technical performance, with low CVs and good linearity across all analytes. Despite interferences at low TBIL and Phosphate concentrations due to lipemia, method comparisons showed strong agreement. The system exhibited efficient turnaround times meeting lab requirements.

The Mindray SAL 8000 demonstrated strong correlation and performance for all routine chemistry and immunoassay parameters, indicating interchangeability with other systems. The Mindray SAL 8000 system's optimal performance makes it ideally suited for medium to large laboratories.

Download link: DOI: 10.7754/Clin.Lab.2019.181228

BS-600M Comparison of Six Methods for HbA1c

> Lab Med. 2024 May 27;Imae034. doi: 10.1093/labmed/Imae034. Online ahead of print.

Interference of hemoglobin variants with HbA1c measurements: comparison of 6 commonly used HbA1c methods with the IFCC reference method

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- 2 Department of Laboratory Medicine, Wuhan Asia General Hospital Affiliated to Wuhan University of Science and Technology, Wuhan, China.
- 3 Department of Laboratory Medicine, Shenzhen Integrated Traditional Chinese and Western Medicine Hospital, Shenzhen, China.

Summary:

This multi-center study examined the impact of common hemoglobin variants on HbA1c measurement systems crucial for diabetes management. In total 6 commonly used methods were assessed using the IFCC reference method.

A total of 63 variant and nonvariant samples with target values assigned by IFCC-calibrated methods were included. The study assessed 6 methods for measuring HbA1c in the presence of HbS, HbC, HbD, HbE, and fetal hemoglobin (HbF): The HbA1c results for nonvariant samples from the 6 methods were in good agreement with the IFCC reference method results. The Bio-Rad D-100, Capillarys 3, Mindray BS-600M, Premier Hb9210, and Roche c501 showed no interference from HbS, HbC, HbD, and HbE. Clinically significant interference was observed for the HLC-723 G8 standard mode. Elevated HbF levels caused significant negative biases for all 6 methods, which increased with increasing HbF concentration.

These findings highlight the importance of considering hemoglobin variants, especially elevated HbF levels, when interpreting HbA1c results in clinical practice.

Download link: DOI: 10.1093/labmed/Imae073

BS-600M Enzymatic Method for HbA1c

> Sci Rep. 2024 May 29;14(1):12289. doi: 10.1038/s41598-024-63261-y.

Analytical performance evaluation of the Mindray enzymatic assay for hemoglobin A_{1c} measurement

Mingyang Li ^{# 1}, Xiongjun Wu ^{# 2}, Weijie Xie ¹, Yu Zeng ¹, Hui Wang ³, Han Chen ³, Anping Xu ⁴, Helu Liu ⁵, Ling Ji ⁶

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- 2 Department of Laboratory Medicine, Shenzhen Integrated Traditional Chinese and Western Medicine Hospital, Shenzhen, China.
- 3 Department of Clinical Laboratory, Wuhan Asia General Hospital Affiliated to Wuhan University of Science and Technology, Wuhan, China.

Summary:

This research study investigated the impact of common hemoglobin variants on HbA1c measurements using various methods, including IFCC-calibrated techniques and the Mindray BS-600M enzyme assay.

Among the methods assessed, the Bio-Rad D-100, Sebia Capillarys 3 TERA, Mindray BS-600M, Premier Hb9210, and Roche c501 showed minimal interference from common variants. The biases in HbA1c levels (6.5% and 9.0%) were caused by LA1c, acetylated hemoglobin, and carbamylated hemoglobin were – 0.71% and – 0.29%, – 1.39% and – 1.28%, and 0.87% and 0.10%, respectively.

These findings emphasize the significance of considering hemoglobin variants, especially HbF levels, for precise HbA_{1c} evaluation.

Download link: DOI: 10.1038/s41598-024-63261-y

BS-600M Blood Lipids for Cardiovascular Disease

> *Cardiovasc Diagn Ther.* 2024 Feb 15;14(1):174-192. doi: 10.21037/cdt-23-369. Epub 2024 Feb 1.

Reference intervals for cardiometabolic risk factors in China: a national multicenter cross-sectional study on an adult population sample

Xuesong Fan ^{# 1}, Xianjun Wang ^{# 2}, Hongmei Zhao ^{# 3}, Daqian Xiong ⁴, Min Hu ⁵, Lixin Wang ⁶, Aiping Pan ⁷, Carlo Gabelli ⁸, Matthew J Budoff ⁹, Hui Yuan ¹

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 - 2 Affiliated Hangzhou First People's Hospital, School of Medicine, Westlake University, Hangzhou, China.
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 - 5 Department of Clinical Laboratory, The Second Xiangya Hospital, Central South University, Changsha, China.
 - 6 Medical Laboratory, General Hospital of Ningxia Medical University, Yinchuan, China.
 - 7 Department of Clinical Laboratory, The First Affiliated Hospital of Guangxi University of Chinese Medicine, Nanning, China.
 - 8 CRIC, Department of Medicine, University Hospital of Padova, Padova, Italy.
 - 9 Lundquist Institute, Harbor-UCLA Medical Center, Torrance, CA, USA.
- # Contributed equally.

Summary:

In a national multicenter study involving 11,333 Chinese adults using Mindray's BS-2000 system, accurate reference intervals for blood lipids and glucose were established.

Regional variances were noted in sd-LDL-C, GluG, and ApoA1. Gender differences existed in HCY, HDL-C, and ApoA1 levels, with age-related increases in GluG and HCY. Notably, females aged 45-55 exhibited significant rises in TG and TC, while females over 55 showed 20% higher TG and TC levels than males.

These Mindray BS-600M national study results aid in setting age- and sex-specific reference values for enhancing cardiovascular disease management strategies.

Download link: DOI: 10.21037/cdt-23-369

BS-200E Renal Function in Visceral Leishmaniasis

> *Res Rep Trop Med.* 2023 Jun 28;14:21-33. doi: 10.2147/RRTM.S410137. eCollection 2023.

Evaluation of Renal Function Profile in Human Visceral Leishmaniasis (Kala-Azar) Patients: A Case of Western Tigray, Ethiopia

Kibrom Gerezgiher Asfaw ¹, Solomon Tebeje Gizaw ¹, Natesan Gnanasekaran ^{1 2}

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Affiliations

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- 2 Regan Institute of Metabolic Therapy, Rasipuram Tk, Namakkal Dt, Tamilnadu, India.

Summary:

In this study conducted in Ethiopia, the renal function profile of Visceral Leishmaniasis (VL) patients was evaluated using data from 100 patients and controls.

Utilizing the Mindray BS-200E automated chemistry analyzer, serum creatinine levels were significantly higher, while urea and estimated glomerular filtration rate (eGFR) were notably lower in VL patients. The results indicate kidney dysfunction in VL, suggesting the disease's impact on renal activities. Specifically, from 100 VL cases, an increased level of serum creatinine, urea, and uric acid was found in 10%, 9% and 15% VL cases, respectively; meanwhile, a decreased serum urea and eGFR have been reported from 33% to 44% VL cases, respectively.

This study using the Mindray BS-200E analyzer underscores the need for further exploration into Visceral Leishmaniasis's effects on various organ functions, emphasizing the search for effective prevention and intervention strategies.

Download link: DOI: 10.2147/RRTM.S410137

BS-300 Lipid Parameters Correlate in TSH

> *Horm Mol Biol Clin Investig.* 2022 Sep 1;44(1):61-65. doi: 10.1515/hmbci-2022-0019.
eCollection 2023 Mar 1.

Level of non-conventional lipid parameters and its comparative analysis with TSH in subclinical hypothyroidism

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¹ Department of Biochemistry, faculty of Medicine & Health Sciences, SGT University, Gurugram, Haryana, India.

Summary:

This study conducted using the Mindray BS-300 Analyzer examined lipid parameters among individuals with subclinical hypothyroidism and their correlation with Thyroid Stimulating Hormone (TSH).

A dataset of forty newly diagnosed subclinical hypothyroidism cases and age/gender-matched controls were used for the study. Utilizing a Mindray BS-300 analyzer, serum lipid profiles were analyzed. Results showed significant elevations in oxidized LDL, lipoprotein (a), apolipoprotein A1, apolipoprotein B, and small dense LDL (sd LDL) in the subclinical hypothyroid group. Positive correlations were found between TSH levels and ox-LDL ($r = 0.85$) and sd LDL ($r = 0.71$).

These results from the Mindray BS-300 Analyzer underscore the potential of these lipid parameters as sensitive indicators of atherogenic dyslipidemia in subclinical hypothyroidism and as novel risk factors for coronary artery disease (CAD).

Download link: DOI: 10.1515/hmbci-2022-0019

Novel G6PD Automated Enzymatic Method

> *BMC Pediatr.* 2022 Nov 23;22(1):678. doi: 10.1186/s12887-022-03740-1.

Effect of neonatal reticulocytosis on glucose 6-phosphate dehydrogenase (G6PD) activity and G6PD deficiency detection: a cross-sectional study

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Summary:

This study assessed the impact of reticulocytosis on blood G6PD activity determination in Thai newborns using a novel automated UV-based enzymatic assay from Mindray.

Results from a dataset of 1,015 newborns indicated the Mindray automated assay detected G6PD deficiency in 6.5% of subjects. Reticulocyte counts were higher in G6PD-deficient newborns. While a correlation between reticulocyte levels and G6PD activity was found in normal newborns, this link was absent in G6PD-deficient subjects.

The Mindray automated method demonstrated high sensitivity (98.4%), specificity (99.5%), and accuracy (99.4%) in detecting G6PD deficiency, with no significant impact from reticulocytosis on detection rates according to qualitative and quantitative assessments.

Download link: DOI: 10.1186/s12887-022-03740-1

BS-2000 CRP in Inflammation

Clinical Trial > BMC Res Notes. 2020 Mar 18;13(1):162. doi: 10.1186/s13104-020-05016-2.

Effect of Gum Arabic (*Acacia senegal*) on C-reactive protein level among sickle cell anemia patients

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Summary:

This retrospective study using the Mindray BS-2000 analyzer examined stored samples for CRP results from a Gum Arabic (GA) and sickle cell anemia trial.

Using the Mindray BS-2000 analyzer, quantitative CRP levels were measured pre and post 12-week Gum Arabic intake. Daily consumption of Gum Arabic significantly reduced CRP (P.V = 0.001) (95% CI, 0.943-3.098), revealing GA's novel anti-inflammatory properties. No correlations were found between CRP and age, fetal hemoglobin, hemolysis markers, or white blood cells.

These CRP results using the Mindray BS-2000 analyzer suggest Gum Arabic could serve as a natural dietary supplement to mitigate disease severity and inflammation in sickle cell patients.

Download link: DOI: 10.1186/s13104-020-05016-2

Anaemia Profile and Inflammation Markers in Stunted Children



Article

Anaemia Profile and Inflammation Markers in Stunted Children Under Two Years in Indonesia

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Summary:

Stunting, a prevalent issue in malnourished Indonesian children, often correlates with inadequate outcomes despite government food programs, potentially due to accompanying anaemia and comorbidities. This study investigated anaemia profiles and inflammation markers in stunted children under two years old.

Utilizing the Mindray BC-5380 hematology analyzers, BS-240 chemistry analyzers for serum iron, and CL-900i analyzer for ferritin examinations, alongside inflammatory marker analysis from BC5380, it identified various anemias like suspected thalassemia (38.1%) and comorbidities such as TB (21.4%).

Combining the study outcomes, it is evident that Mindray instruments played a crucial role in blood and iron metabolism testing, furnishing precise and reliable data support. These findings contribute to refining diagnostic and monitoring approaches for related conditions, offering valuable insights for clinical practices and patient care.

Download link: DOI: 10.3390/children11111315



The CL-2600i provides reliable results and increased operational efficiency, empowering mid-volume laboratories.



Chemiluminescence Immunoassay Literature

CL-1200i hs-cTnI Assay

> Clin Chem Lab Med. 2024 May 28. doi: 10.1515/cclm-2024-0352. Online ahead of print.

Analytical validation of the Mindray CL1200i analyzer high sensitivity cardiac troponin I assay: MERITnI study

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- 4 Department of Laboratory Medicine & Pathology, 5532 Hennepin Healthcare/Hennepin County Medical Center, Minneapolis, MN, USA.
- 5 Department of Laboratory Medicine & Pathology, University of Minnesota School of Medicine Minneapolis, MN, USA.

Summary:

This multicenter study led by Fred S. Apple, one of the world's leading cardiac marker biochemists, performed an analytical validation study of the Mindray high-sensitivity cardiac troponin I (hs-cTnI) assay.

The Mindray hs-cTnI assay met criteria to be considered as a highly sensitive and accurate hs-cTn assay. LoB and LoD were < 0.1 ng/L and 0.1 ng/L, respectively. Repeatability had a coefficient of variation 1.2-3.8 %, and within-laboratory imprecision 1.7-5.0 %. The measuring interval ranged from 1.1 to 28,180 ng/L.

Analytical observations of the Mindray hs-cTnI assay demonstrated excellent LoB, LoD, precision, linearity and analytical specificity, that were in alignment with the manufacturer's claims and regulatory guidelines for hs-cTnI. The assay is suitable for clinical investigation for patient-oriented studies.

Download link: DOI: 10.1515/cclm-2024-0352

CL-1200i hs-cTnI vs Beckman

> Clin Chem Lab Med. 2024 Jan 8;62(7):1433-1437. doi: 10.1515/ccim-2023-1448. Print 2024 Jun 2!

Analytical evaluation of the novel Mindray high sensitivity cardiac troponin I immunoassay on CL-1200i

Giuseppe Lippi ¹, Laura Pighi ¹, Elisa Paviati ¹, Davide Demonte ¹, Simone De Nitto ¹, Matteo Gelati ¹, Martina Montagnana ¹, Giorgio Gandini ², Brandon M Henry ³, Gian Luca Salvagno ¹

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- 3 Clinical Laboratory, Division of Nephrology and Hypertension, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA.

Summary:

This multicenter study was designed to evaluate the analytical performance of the new Mindray highly sensitive cardiac troponin I (hs-cTnI) chemiluminescent immunoassay on Mindray CL-1200i against the Beckman Access hs-TnI assay.

The Mindray hs-cTnI LOB and LOD were 0.32 and 0.35 ng/L, whilst the functional sensitivity (expressed as cTnI value with <10 % imprecision), was 0.35 ng/L. The Spearman's correlation between Mindray hs-cTnI and Access hs-TnI was 0.97, with mean bias of 7.2 % (95 % CI, 2.6-11.9 %).

This evaluation of the novel Mindray hs-cTnI immunoassay on CL-1200i demonstrated that the overall performance is comparable to that of other commercially available hs-cTnI techniques, making it a viable alternative to other methods.

Download link: DOI: 10.1515/ccim-2023-1448

CL-1200i NT-proBNP vs Roche NT-proBNP

Comparative Study > BMC Cardiovasc Disord. 2024 Jul 5;24(1):341.

doi: 10.1186/s12872-024-03994-w.

Analytical and clinical performance evaluation of a new NT-proBNP assay

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Summary:

The study evaluated the performance of the Mindray N-terminal pro-B-type natriuretic peptide (NT-proBNP) in a healthy population in China.

In males, the 97.5th centile NT-proBNP concentration at age < 45, 45 to 54, 55 to 64, 65 to 74 and ≥ 75 were 89.4 ng/L, 126 ng/L, 206 ng/L, 386 ng/L and 522 ng/L, respectively. In females, the concentration of NT-proBNP at the same age was 132 ng/L, 229 ng/L, 262 ng/L, 297 ng/L and 807 ng/L, respectively.

The Mindray NT-proBNP assay showed increased levels in both males and females with age, with higher levels in women. It performs well and aligns with manufacturer specifications and the Roche NT-proBNP assay. We recommend adjusting cutoff values based on demographic factors.

Download link: DOI: 10.1186/s12872-024-03994-w

CL-6000i vs Siemens in Thyroid Assays

> Ann Transl Med. 2022 Oct;10(20):1133. doi: 10.21037/atm-22-4589.

Comparison on the consistency of Mindray and Siemens chemiluminescence analyzers for detecting FT3, FT4 and TSH in patients with hyper- and hypothyroidism

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Summary:

This study aimed to examine the consistency of the Mindray and Siemens full-automatic chemiluminescence analyzers in detecting serum free triiodothyronine (FT3), free thyroxine (FT4) and thyroid stimulating hormone (TSH) in patients with hyper- or hypothyroidism.

There was a good linear correlation between the test results of Mindray and Siemens ($R^2 > 0.90$). Bland-Altman consistency analysis indicated that the difference between the two systems was acceptable. AUC of FT3, FT4 and TSH detected by the two systems was higher than 0.80 in each group, showing no significant difference between them (both $P > 0.05$).

Mindray and Siemens chemiluminescence analyzers are highly consistent in detecting FT3, FT4 and TSH in both hyper- and hypothyroidism patients.

Download link: DOI: 10.21037/atm-22-4589

CL-1200i vs Abbott Architect Infectious Markers

> Diseases. 2023 Jun 8;11(2):83. doi: 10.3390/diseases11020083.

Performance Evaluation of the New Chemiluminescence Immunoassay CL-1200i for HBV, HIV Panels

Eleonora Nicolai ¹, Serena Sarubbi ¹, Martina Pelagalli ¹, Valerio Basile ¹, Alessandro Terrinoni ^{1 2}, Marilena Minieri ^{1 2}, Oreste Cennamo ², Sandro Grelli ^{1 2}, Sergio Bernardini ^{1 2}, Massimo Pieri ^{1 2}

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Summary:

The aim of this study was to compare the performance of the Abbott system and of the new analyzer Mindray CL-1200i in the detection of HBV- and HIV-infections.

Precision study, linearity, and carryover were performed on the results obtained. The agreement between the results of the Abbott and Mindray CLIA ranged from 99% to 100% and the discrepancy rate from 0% to 1%.

The measurements demonstrated that the Mindray CL-1200i platform offers high-level performance with accurate and consistent test results similar to Abbott infectious marker results. The Mindray CL-1200i system can be used effectively for assessment of HBV- and HIV-infections

Download link: DOI: 10.3390/diseases11020083

PSA Assay vs Beckman/Roche/Abbott

> *Transl Androl Urol.* 2023 Feb 28;12(2):261-270. doi: 10.21037/tau-23-29. Epub 2023 Feb 23.

Consistency and diagnostic accuracy of 4 assays in the detection of the total and free prostate-specific antigen

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Summary:

The currently available mainstream assays for PSA were based on Western populations, but it is not clear whether these assays yield different results in prostate cancer (PCa) screening in Chinese populations. This study evaluated Roche, Abbott, Beckman and Mindray total and free PSA results in the Chinese population.

The tPSA levels detected by the Roche, Abbott, and Mindray showed good consistency with Beckman but not with fPSA levels. Compared to the Beckman tPSA values, the measured values were 1.1% higher for Roche, 2.1% higher for Abbott, and 6.7% higher for Mindray. The fPSA levels measured by Roche, Abbott, and Mindray were 5.4% lower, 22.1% higher, and 4.6% higher than Beckman, respectively.

In summary, when the tPSA is in the range of 2–10 ng/mL, the tPSA values measured by the Abbott, Roche, Mindray, and Beckman assays (using the Hybritech calibration) have good consistency, and the results are almost interchangeable. However, the consistency of the fPSA measurements is unsatisfactory, and the cut-off value of %fPSA (i.e., 16%) is not applicable to every assay. Each assay must be carefully evaluated to establish its own cut-off value.

Download link: DOI: 10.21037/tau-23-29

CL-2000i AMH Assay vs Roche Cobas

> *J Clin Lab Anal.* 2021 Apr;35(4):e23734. doi: 10.1002/jcla.23734. Epub 2021 Mar 4.

Performance characteristics of the Mindray chemiluminescence anti-Müllerian hormone assay

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Summary:

The aim of this study was to define the performance characteristics of the Mindray chemiluminescence assay for anti-Müllerian hormone (AMH) detection against the Roche Cobas assay.

The intra-assay and total imprecision percent coefficients of variation for low and high AMH serum levels were 2.74%/ 3.01% and 5.41%/5.35% respectively. The limits of blank, detection, and quantitation were 0.007, 0.01, and 0.03 ng/ml, respectively. The coefficient of determination (R²) of the Mindray versus Roche assays was 0.9713 with 411 samples with AMH concentrations ranging from 0.014 to 22.1 ng/ml. The slope and intercept of the regression equation were 0.9687 and 0.3419, respectively.

The Mindray CL-2000i AMH assay demonstrated acceptable analytical performance under routine conditions and is suitable for determining AMH levels in serum samples.

Download link: DOI: 10.1002/jcla.23734

hs-cTnI Assay Reference Interval

> *Transl Pediatr.* 2024 Jun 30;13(6):908-920. doi: 10.21037/tp-24-98. Epub 2024 Jun 24.

Specific reference interval for high-sensitivity cardiac troponin I among healthy children in Wuhan, China

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Summary:

This study aimed to establish a preliminary pediatric hs-cTnI RI for newborns, children, and adolescents in Wuhan, China.

A dataset of 1,355 pediatric participants from which serum hs-cTnI concentrations in 1,332 children were measured. The serum overall P50 and 95% interval range (P2.5-P97.5) of serum hs-cTnI was 0.41 (0.00, 44.31) ng/L. This was higher in males of 0.47 (0.00, 44.90) ng/L than in females of 0.36 (0.00, 44.17) ng/L ($P < 0.01$). Age- and sex-specific differences in hs-cTnI levels were observed.

This study preliminarily established age- and sex-specific serum hs-cTnI RIs using the Mindray CL-6000i system in healthy children in Wuhan, China.

Download link: DOI: 10.21037/tp-24-98

Thyroid Assays Pediatric Reference Interval

> *Transl Pediatr.* 2021 Oct;10(10):2479-2488. doi: 10.21037/tp-21-389.

Age- and sex-specific reference intervals for thyroid hormones in a Chinese pediatrics: a prospective observational study of 1,279 healthy children

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- 3 Department of Laboratory Medicine, Wuhan Hankou Hospital, Wuhan, China.

Summary:

This study aimed to establish thyroid hormone RIs for a Chinese pediatric population according to appropriate age- and sex-specific partitioning using Mindray Thyroid assays.

Quantile testing revealed that the median (P50) and RIs [2.5th percentile (P2.5)-97.5th percentile (P97.5)] for TSH, FT3, T3, and T4 of males differed significantly from those of females ($P < 0.05$), except for FT4 ($P = 0.483$).

Pediatric RIs of thyroid hormones display age- and sex-specific trends. The RIs established in this study will improve the accuracy of TSH assay result interpretations and clinical decision-making in clinical laboratories that utilize the Mindray analytical platform.

Download link: DOI: 10.21037/tp-21-389

Vitamin D Assays and Heart Failure

> [Biomolecules](#). 2023 Oct 26;13(11):1578. doi: 10.3390/biom13111578.

Total 25-Hydroxyvitamin D Is an Independent Marker of Left Ventricular Ejection Fraction in Heart Failure with Reduced and Mildly Reduced Ejection Fraction

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Summary:

This multicenter study using Mindray analyzers addressed total 25-hydroxyvitamin D (25(OH)D), serum albumin, and uric acid (UA) levels, focusing mainly on vitamin D deficiency, as potential markers of left ventricular (LV) systolic dysfunction in heart failure (HF) with reduced and mildly reduced ejection fraction (HFrEF, HFmrEF).

Statistically significant positive correlations were found between left ventricular ejection fraction (LVEF), 25(OH)D, serum UA, and albumin, respectively ($p = 0.008$, $p = 0.009$, and $p = 0.001$).

According to our current findings, 25(OH)D is closely associated with LVEF, further supporting the need to establish correct vitamin D supplementation schemes and dietary interventions in HF. The changes in LVEF, 25(OH)D, serum UA, and albumin levels in HFrEF and HFmrEF indicate a similar pathophysiological background.

Download link: DOI: 10.3390/biom13111578

Tumor Markers Reference Intervals

Multicenter Study > [J Clin Lab Anal](#). 2021 Jun;35(6):e23816. doi: 10.1002/jcla.23816. Epub 2021 May 12.

Age-stratified and gender-specific reference intervals of six tumor markers panel of lung cancer: A geographic-based multicenter study in China

Yan Li ¹, Ming Li ², Yi Zhang ³, Jianping Zhou ⁴, Li Jiang ⁵, Chen Yang ⁶, Gang Li ⁷, Wei Qu ⁸, Xinhui Li ⁹, Yong Chen ¹⁰, Qing Chen ¹⁰, Wei Wang ¹⁰, Shukui Wang ⁸, Jin Liang Xing ¹¹, Huayi Huang ^{10, 12}

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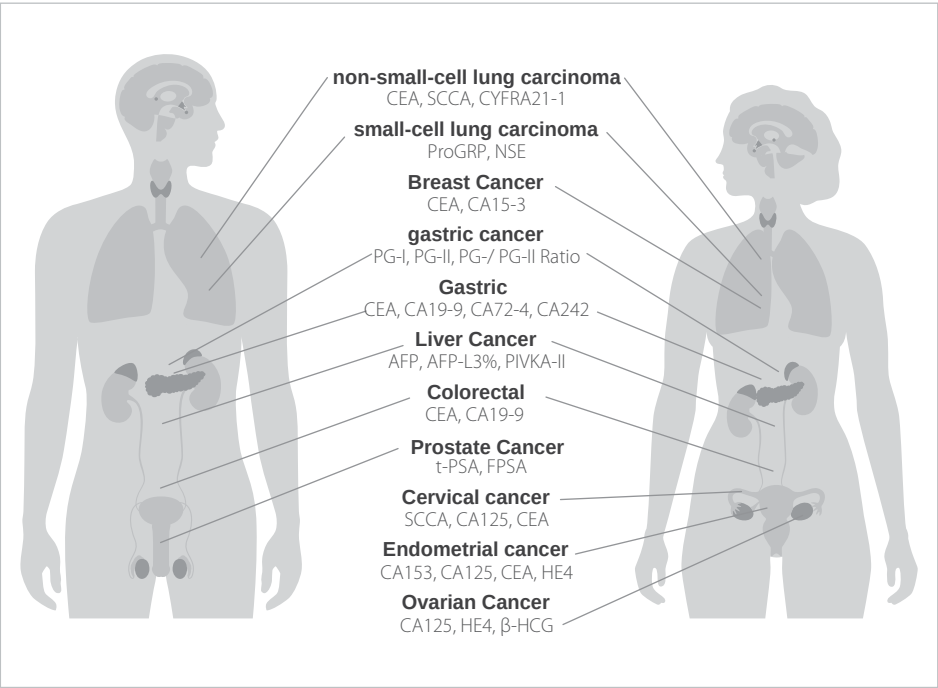
Summary:

This multicenter study aimed to establish a RI for each of 6 lung cancer biomarkers for use in the whole country of China using the Mindray analyzer platform.

The age-stratified, gender-specific RIs for ProGRP, NSE, SCC, CEA, CYFRA21-1, and HE4 lung cancer biomarkers in the Chinese population have been established as described in the results and discussion in this work. In addition, various levels of the six lung cancer biomarkers among nine geographical locations in China have been observed.

A RI for each of six lung cancer biomarkers has been established utilizing the Mindray analyzer platform. The results from this study would be helpful for clinical laboratories in interpreting the analytical results and for clinicians in patient management.

Download link: DOI: 10.1002/jcla.23816



The Mindray Tumor Panel offers 22 tumor markers, making it the most comprehensive provider of tumor markers.

CA125/HE4 in Ovarian Cancer

Transl Cancer Res. 2024 Aug 31;13(8):4474-4484. doi: 10.21037/tcr-24-1107. Epub 2024 Aug 21.

The diagnostic performance of the Mindray system in detecting CA125 and HE4 for patients with ovarian cancer

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- 3 Department of Obstetrics and Gynecology, Julius-Maximilians University, Medical School Würzburg, Germany.

Summary:

This multicenter study sought to assess the performance of the Mindray system against the Roche Cobas system in detecting CA125 and HE4 for ROMA score calculation in clinical settings.

For the premenopausal Ovarian Cancer (OC) patients, the AUC values for the ROMA score, HE4, and CA125 were 0.866, 0.852, and 0.879, respectively, using the Roche system, and 0.911, 0.902, and 0.883, respectively, using the Mindray system. For the postmenopausal ovarian cancer (OC) patients, the AUC values for the ROMA score, HE4, and CA125 were 0.962, 0.920, and 0.953, respectively, using the Roche system, and 0.966, 0.924, and 0.959, respectively, using the Mindray system.

The Mindray and Roche systems provide consistent results. The Mindray system generates similar results to Roche and can be used effectively to detect HE4 and CA125 for ROMA score calculations.

Download link: DOI: 10.21037/tcr-24-1107

sCD14-ST Biomarker in Osteomyelitis

> Diagnostics (Basel). 2024 Jul 23;14(15):1588, doi: 10.3390/diagnostics14151588.

sCD14-ST and Related Osteoimmunological Biomarkers: A New Diagnostic Approach to Osteomyelitis

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- 7 Department of Experimental and Clinical Pathology, IRCCS Istituto Auxologico Italiano, 20149 Milan, Italy.

Summary:

The present study aims to investigate the potential diagnostic role of a panel of osteoimmunological serum biomarkers in the clinical approach to osteomyelitis (OM).

Mindray sCD14-ST displayed a very significant difference between OM-positive and -negative patients at T0, which remains quite significant also at T1, 2 hours post-surgery. This strong ability to distinguish OM-positive and -negative patients is confirmed by a very high Mindray sCD14-ST ROC AUC (0.978).

The Mindray study results, to our knowledge, demonstrate for the first time the diagnostic and early prognostic role of sCD14-ST in OM patients. In addition, the study highlights a relevant diagnostic role of SuPAR, the chemokine CCL2, the anti-inflammatory cytokine IL-10, the Wnt inhibitors DKK-1 and Sclerostin, and the RANKL/OPG ratio. Moreover, CCL2 and SuPAR also exhibited early prognostic value using the Mindray platform.

Download link: DOI: 10.3390/diagnostics14151588



TDR X060/120 Automated Blood Culture System can achieve rapid and automated growth detection bacteria in sterile body fluid, with advanced irreversible colorimetry technology, designed for all labs with easy-to-use workflow.

Microbiology Literature

TDR-X060 vs bioMérieux BacT/Alert

Comparative Study > Acta Clin Belg. 2024 Jun;79(3):168-173.
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Comparison of time-to-detection of Mindray TDR and BacT/ALERT®3D blood culture systems using simulated blood cultures

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Summary:

Available blood culture systems have been developed to shorten the time to detection (TTD) of positive blood cultures (BCs). This study aimed to evaluate the performance of the Mindray TDR automatic BC system by comparing it with the BacT/ALERT®3D system.

At both 10 CFU/ml and 100 CFU/ ml dilution, there was no significant difference between the two systems (Mindray TDR-X060 and BacT/Alert) in terms of mean detection times for all isolates.

In conclusion the two systems with similar operating principles showed different concentration-dependent performances in terms of positivity detection times depending on the type of microorganism. Mindray TDR-X060 system has been found to be safe to use at high concentrations with this at lower concentrations further comparative studies are needed on the newly introduced Mindray system.

Download link: DOI: 10.1080/17843286.2024.2376224

TDR-X060 vs Autobio/DL/Scenker/bioMérieux 3D

> EBioMedicine. 2024 Mar;101:105004. doi: 10.1016/j.ebiom.2024.105004. Epub 2024 Feb 12.

Affordable blood culture systems from China: in vitro evaluation for use in resource-limited settings

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Summary:

Bloodstream infections (BSI) pose a significant threat due to high mortality rates and the challenges posed by antimicrobial resistance (AMR). In this diagnostic comparative study, we screened the Chinese blood culture market for CMBCS for potential use in RLS

Overall, all evaluated Automated continuous monitoring blood culture (CMBCS) demonstrated (Mindray/Autobio/DL/Scenker) good performance with high yield (96.7–100%) and specificity (97.5–100%), comparable to the reference system (bioMérieux 3D).

The evaluated Chinese systems, including the Mindray TDR-X060, show promise in improving BSI diagnosis and management in resource-limited settings, contributing to efforts to combat antimicrobial resistance and enhance patient care.

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TDR-300B for Antimicrobial Surveillance in Sepsis

> BMC Infect Dis. 2020 Feb 21;20(1):161. doi: 10.1186/s12879-020-4886-2.

Sepsis in cancer patients residing in Zimbabwe: spectrum of bacterial and fungal aetiologies and their antimicrobial susceptibility patterns

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Summary:

This multicenter study using the Mindray TDR-X120 blood culture system and TDR-300B auto-identification analyzer aimed to ascertain the microbial agents of sepsis and their antimicrobial susceptibility patterns among hospitalized pediatric and adult patients with cancer in Zimbabwe.

10 (66.7%) extended spectrum β -lactamase (ESBL) amongst the *E. coli* and *K. pneumoniae* isolates. Ten (66.7%) of the *Staphylococcus* spp. were methicillin resistant. Amikacin and meropenem showed 85.7 and 95.2% activity respectively against all Gram-negative isolates, whilst vancomycin and linezolid were effective against 96.2 and 100.0% of all Gram-positive isolates respectively.

The Mindray Microbiology analyzers performed well in this nationwide study. A nationwide survey on microbial aetiologies of sepsis and their susceptibility patterns would assist in the guidance of effective sepsis empiric antimicrobial treatment among patients with cancer.

Download link: DOI: 10.1186/s12879-020-4886-2

TDR NH-96 Kit in Research of Haemophilus Seminalis

> Microbiol Spectr. 2023 Aug 17;11(4):e0477222. doi: 10.1128/spectrum.04772-22. Epub 2023 Jun 29.

Comparative Genomic Analysis Reveals Genetic Diversity and Pathogenic Potential of Haemophilus seminalis and Emended Description of Haemophilus seminalis

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Summary:

In this study the Mindray TDR NH-96 kit was used to investigate distribution of *Haemophilus Seminalis* (*H. seminalis*) in the human, population, its genomic diversity, and its pathogenicity.

Results showed firstly, *H. seminalis* has an open pangenome. Secondly *H. seminalis* was found to possess most of the virulence genes of *H. influenzae*.

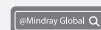
This study using the Mindray TDR NH-96 kit provides a more accurate identification of *Haemophilus* isolates for use in the clinical laboratory and a better understanding of the clinical significance and genetic diversity in human environments.

Download link: DOI: 10.1128/spectrum.04772-22

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