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REVIEW ARTICLE

Assessing the Reliability of Commercially Available Point of Care in Various Clinical Fields

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Abstract:

Updated and precise molecular diagnostics are essential in disease identification, treatment and management. Conventional technologies are limited to laboratories, which are expensive, require moderate to great volumes of biological fluids and generally create great discomfort among patients. This review discusses some key features of commercially available point of care (POC) devices, such as time to provide results, accuracy and imprecision, in several medical and veterinary fields. We searched Pubmed/Medline using the keywords “point” “of” “care” “device”, selected papers from 1984 to 2019 on the basis of their content and summarized the features in tables.

Fast turnaround time and overall good reliability, in terms of accuracy and imprecision, were observed for most of POCs included in the research.

POC devices are particularly useful for clinicians since they hold the potential to deliver rapid and accurate results in an inexpensive and less invasive way with an overall improvement of patients' quality of life in terms of time spent at the point-of-care and sample volume withdrawn. These features gain great relevance also in the veterinary practice, where patients’ compliance is generally poor, available sample volumes are quite far from the human ones and analysis costs are higher.

Keywords: Disease, POC, Accuracy, Imprecision, Human, Veterinary.

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1. INTRODUCTION

The point-of-care (POC) is generally used outside the central laboratory to facilitate the patient’s faster diagnosis and treatment. It is one of the innovations that impact potentially on the quality and rapidity of care, as well as on system redesign of a more patient-centred care approach [1, 2]. POCs are commercially available either as small bench-top analyzers or as hand-held devices. The latter are used by patients for homecare and by healthcare professionals. If, on one hand, laboratory results can take from several hours to few days, on the other hand, POCs reduce analysis time from hours to few seconds, therefore, gaining relevant importance especially in emergency conditions (Table **1**).

To evaluate a safe and reliable POC, it is important to consider its sensitivity (the percentage of true positive results), specificity (percentage of true negative results) and positive and negative predictive values (PPV, NPV, respectively) according to the disease prevalence in the considered population [3]. The analytical performance of a device is assessed through imprecision, quantified by calculating the within-run coefficient of variation (CV) from the test result data of a given device, and accuracy, estimated by means of a coefficient of correlation (r) from the set of data obtained from the two devices-analyzer (POC) and a reference or standard instrument [4].

This review firstly considers the commercially available POCs, sorting them by medical application and analyzing some key features such as time to provide results, accuracy and imprecision. In fact, most of the current reviews on POC dealt with singular medical applications providing information about their performance with respect to centralized laboratory instruments. In this sense, the aim of this review was to provide human and animal healthcare a useful tool for a correct choice of a POC for a specific disease, particularly, in this modern era where the concepts efficiency and costs have become a public health concern.

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2. MATERIALS AND METHODS

The aim of this review was to provide the actual status of point of care (POC) devices highlighting some key features, such as time to result, accuracy and imprecision, in several medical fields including ematobiochemistry, cardiology, infectious disease, andrology and gynecology, toxicology, oncology, genetics, dentistry ophthalmology ultrasology and even veterinary medicine.

We searched Pubmed/Medline and other external sources using the keywords "point of care device". Selected papers from 1984 to 2019 were chosen on the basis of their content and included. Moreover, some technical data were also downloaded from website of the POC's manufacturer.

2.2. Point of Care in Human Practice

2.2.1. Ematobiochemistry

Rapid evaluation of blood parameters, in particular, glucose, electrolyte and metabolic parameters, gained even more attention in the last years due to the wide diffusion of POC devices also among non-laboratory trained individuals including patients themselves [5, 6]. Most of these devices are based on a photometric method, share an overall high degree of accuracy and are characterized by a rapid turnaround time of test results providing them an edge over conventional central laboratory analyzers (Table **1**).

2.2.2. Diabetes

Glucose meters are used worldwide providing fast analysis of blood glucose, glycated hemoglobin, β-hydroxybutyrate, TSH and free T4 levels, allowing the management of hypoglycemic and hyperglycemic disorders [115]. They mainly rely on an electrochemically-based measurement test, which reduced the time-to-result from minutes to few seconds requiring blood volumes as little as few microliters [116]. Besides the need to monitor glycemia to reduce morbidity and mortality, the primary requirement of clinicians is the reliability of glucose meters (inaccuracy and imprecision remain fundamental) even in the presence of interfering substances including but not limited to ascorbate, hematocrit and maltose [117]. Despite the presence of many other factors able to undermine the accuracy of such devices, the degree of precision reached by current POCs is very high, although their handling should be generally left to a well-trained staff (Table **2**) [118].

2.2.3. Cardiology

The need for enabling a rapid assessment of patients with chest discomfort, both in an ambulance and emergency rooms, as well as the management of bleeding and clotting risks and myocardial infarction prevention led to a rapid increase in technological advancements of POC devices [155]. Among cardiac biomarkers, cardiac troponins gained great relevance with respect to creatine kinase [156, 157]. B-Type Natriuretic Peptide has been successfully used to discriminate between heart failure symptoms and shortness of breath due to pulmonary causes [158], nevertheless also high sensitivity c-reactive protein, D-dimer, myoglobin and N-terminal pro-B-type natriuretic peptide are also assessed [159].

Moreover, a rapid turnaround time, ranging from less than 20 minutes to few seconds, has now been generally achieved by all POC devices, thus allowing an immediate and effective patient triage (Table **3**) [160, 161].

Table 1. Differences between laboratory analysis and POCTs times.

LABORATORY ANALYSIS	POCT
1-Test requested	1-Test ordered
2-Specimen obtained	2-Specimen obtained
3-Specimen processed	3-Specimen analyzed
4-Specimen analyzed	4-Therapy prescribed by clinician
5-Results reviewed by qualified staff	
6- Therapy prescribed by clinician	

Table 2. Commercially available POC devices in Ematobiochemistry.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Clini5 (Callegari S.r.l., Parma, Italy) [7]	TC, HDL cholesterol, LDL cholesterol, TG, Hb, HCT, RBC, UA, lac	10 - 180 seconds	CV = 1.37 - 5.38%	r = 0.75 - 0.99
	FORT, FORD, Redox Index, ALT, AST and AST/ALT	5 - 10 minutes		
LeadCare II blood lead analyser® (Magellan Diagnostics, USA) [8]	lead	3 minutes	CV = 1.7 - 1.8%	r = 0.94
Spotchem EZ® (Menarini, Italy) [9]	TP, ALB, CR, TB	5 minutes	CV = 1.9 - 4.7%	r = 0.97- 0.99
iSTAT creatinine test® (Abbott, USA) [10 - 14]	hct, TCO_2, pO_2, pCO_2, Na^+, K^+, Cl^-, lac, cardiac markers, coagulation factors	3 minutes	CV = 0.4 -3.4%	r = 0.99

(Table 2) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
StatStrip Lactate® (Nova Biomedical, Waltham, MA, USA) [15 - 17]	fetal scalp lac	13 seconds	CV = 5.72%	r = 0.99
iSTAT-1® (Nova Biomedical, Waltham, MA, USA) [18 - 21]	lac	2 minutes	CV = 3.1 - 7.27%	r = 0.94 - 0.97
StatStrip-Lactate® (Abbott, Princeton, USA) [18, 22, 23]	lac	13 seconds	CV = 2.6 - 5.1%	r = 0.90
qLabs Electrometer Plus® (Micropoint Biotechnologies) [24]	PT, INR, aPTT	7 minutes	CV = 5%	r = 0.71 - 0.90
IRMA (DIAMETRICS, ChemoMedica-Austria, Vienna, Austria) [25, 26]	pH, pCO_2, pO_2, Na+, K+, iCa+, HCO_3−, CO_2, TCO_2, BEb, BEecf, O_2SAT	< 2 minutes	CV = 0.2 - 1.9%	r = 0.97- 0.99
GEM Premier 3000/4000 (Instrumentation Laboratory, Lexington, MA, USA) [4, 20, 25, 27, 28]	tHb, COHb, MetHb, O2Hb, HHb, Na^+, K^+, Cl^-, Ca^{2+}, glucose, lac, hct	95 seconds	CV = 0.2 - 4.0%	r > 0.92
Stat Profile Critical Care Xpress analyzer (Nova Biomedical, Waltham, MA, USA) [25, 29]	pH, pCO_2, pO_2, glucose, urea, CR, Na^+, K^+, Cl^-, iCa, iMg, tHb, O_2Hb, COHb, HHB, MetHB, SO_2	52 seconds	CV = from < 5.7 to 13.8%	r = 0.91 - 0.97
Rapidpoint 405 (Siemens Healthcare, Sudbury, UK) [25, 30]	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, glucose, hct, tHb, HHb, O_2Hb, SO_2, COHb, MetHB, TB	1 minute	CV = from 0 to > 2.4%	r = 0.94 - 1.04
ABL 700/725/825/90-FLEX (Radiometer Medical A/S, Bronshoj, Denmark) [25, 31, 32]	pH, pCO_2, pO_2, cK^+, cNa^+, cCl^-, cCa^{2+}, ctHb, sO_2, FO_2Hb, FCOHb, FMetHb, FHH, FHbF, ctBil, glucose, lac	35 seconds	CV = < 3%	r = 0.87
Cobas b 123 (Roche Diagnostics, Graz, Austria) [25, 33]	pCO_2, pO_2, iCa^{2+}, K^+, glucose, lac, tHb	2 minutes	CV = 0 - 6%	r = 0.89 - 0.99
Nova Lactate plus (Nova Biomedical, Waltham, MA, USA) [25, 34]	lac	13 seconds	CV = 0%	r = 0.99
Rapid lab 865 (Siemens, Germany) [25, 35]	pH, pO_2, pCO_2, Ca^{2+}, Na^+, K^+, glucose, lac, Hb	1 minute	CV = from < 2 to < 3%	r = 0.96 - 0.99
iSTAT-1 (Hewlett Packard, Les Ulis, France) [36]	Na^+, K^+, Cl^-, glucose, urea, nitrogen, hact, PO_2, PCO_2, pH	< 2 minutes	CV < 10%	r = 0.83 - 0.98
Stat Sensor® (Nova biomedical, Waltham, USA) [37 - 40]	CR	30 seconds	CV = 6.4 - 8.9%	r = 0.99
STAT-Site® M Hgb (POCD, Australia) [41]	Hb	50 - 120 seconds	CV = 2.9 - 4.2%	r = 0.96
Nova 16 Electrolyte/Chemistry Analyzers® (NovaBiomedical, USA) [42]	Na^+, K^+, Cl^-, TCO_2, Ca^{2+}, Mg^{2+} Li^{2+}, TCa, glucose, BUN, CR, hct, pH	36 seconds	CV = 0.4 - 26%	r = 0.90 - 0.99
Microsemi CRP® (HORIBA, Japan) [43]	blood cell count	4 minutes	CV = 5 - 10%	r ≥ 0.99
BR-501® (Apel, Japan) [44]	TBL	Few seconds	CV = 5%	r = 0.93
Accusport® (Boehringer Ingelheim,USA) [45 - 48]	lac	1 minute	CV = 4.6 - 7%	r = 0.99
Accutrend® Lactate (Accusport International) [49, 50]	lac	1 minute	CV = 1.8 -3.3%	r = 1.03
Accutrend® Plus (Roche Diagnostics, Belgium) [51, 52]	TC, TG, glucose, lac	3 minutes	CV = 3.4 - 3.7%	r ≥ 0.80
BeneCheck® Plus (General Life Biotechnology Ltd, Taiwan)	TC, glucose, uric acid	30 seconds	CV = 3.1 - 6.9%	r = 0.89
Piccolo xpress® Chemistry Analyzer (Abaxis Inc, USA) [53, 54]	Na^+, K^+, Cl^-, Ca^{2+}, TCO_2, AST, ALT, TBL, ALP, BUN, CR, ALB, TP, glucose	12 minutes	CV = 0 - 5.6%	r = 0.98
CardioChek® PA (Polymer Technology Systems Inc, USA) [55 - 58]	TC, HDL cholesterol, TG, direct LDL, glucose, ketones, CR	< 2 minutes	CV = 4.4 - 7.4%	r > 0.84
Cholestech® LDX (Alere, USA) [55, 57, 59]	TC, HDL cholesterol, LDL cholesterol, TG, glucose	5 minutes	CV = 2.6 - 6.2%	r > 0.90

(Table 2) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Reflotron Plus® (Roche Diagnostics, Belgium) [60]	K+, CR, CK, α-Amylase, Hb, pancreatic amylase, glucose, Urea, AST/GOT, TC, ALT/GPT, TG, γ-GT, HDL cholesterol, uric acid, TBL, LDL, cholesterol, ALP/GOT	2-3 minutes	CV = 5%	r = 0.98
HPS MultiCare (Biochemical System International, Arezzo, Italy) [61]	TC, TG	2-3 minutes	CV = 4.51%	r = 0.94 - 0.99
CoaguChek® XS Plus (Roche Diagnostics, Belgium) [61 - 76]	INR	< 1 minute	CV = 2%	r = 0.96
PlaCor PRT® (PlaCor, Inc.) [77, 78]	shear-induced platelet aggregation	10 minutes	CV = 12.9%	r = -0.05 - 0.19
VerifyNow® P2Y12 (Accumetrics, Inc., San Diego, CA, USA) [79, 80]	Platelet response to P2Y12 inhibitor	10 minutes	CV = 8%	r = 0.66
ROTEM® (Tem International GmbH, Germany) [81]	platelet function	5-10 minutes	CV = 1.2 - 4.4%	r = 0.99
FRAS 4 EVOLVO (H&D, Parma, Italy) [82]	plasma antioxidant power	2-5 minutes	CV = 4.17%	r = 0.99
CompoLab™ (Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany)	Hb	< 2 seconds		
Spinit (Biosurfit SA, Lisboa, Portugal) [83]	CRP, hct, WBC, neutrophils, lymphocytes, monocytes	< 12 minutes	CV = 1.8 -10.1%	r = 0.83 - 0.99
HemoScreen (PixCell Medical Technologies, Yokneam Ilit, Israel) [84]	WBC, RBC, HGB, hct, PLT, neutrophils, lymphocytes and eosinophils	5 minutes	CV = 0.58 - 39.4%	r = 0.82 - 0.96
Radical-7 Pulse Co-Oximeter (Masimo Corporation, Irvine, USA) [85]	SpHb	Few seconds	CV = 2.8%	r = 0.97
StatStrip Xpress Lactate Meter (Nova Biomedical, Waltham, MA, USA) [86]	lac	13 seconds	CV = 5 - 9%	r = 0.97 - 0.98
Pronto-7 (Masimo Corporation, Irvine, USA) [20, 86, 87]	Hb	Few seconds	CV = 1.5%	r = 0.83
Liaison® Calprotectin (Diasorin, Saluggia, Italy) [88, 89]	calprotectin	35 minutes	CV = 2.8 - 4.7%	r = 0.95
Quantum Blue® (Bühlmann-Alere®) [89, 90]	calprotectin	12-15 minutes	CV = 22%	r = 0.94
Mission® (Acon biotech, San Diego, USA) [91]	hct	< 15 seconds	CV = -5.5 - 5.1%	r = 0.93
B-722 LAQUAtwin (Lt, Horiba, Japan) [92]	Na^+	Few seconds	CV = -0.4 - 0.2%	r = 0.99
HemoCue® WBC DIFF (HemoCue®, Sweden) [26]	eosinophils	5 minutes	CV = 1 - 13.7%	r = 0.85
Rainbow R20L® (Masimo Corporation, Irvine, USA) [71]	Hb	Few seconds	CV = 2.8%	r = 0.97
B.R.A.H.M.S PCT direct™ (Thermo Fisher Scientific Inc., Waltham, USA) [93]	PCT	25 minutes	CV < 20%	r = 0.96
ABSOGEN™ (Bumyoungbio, Inc., Suwon, Korea) [94]	PCT	10 minutes	CV < 15%	r = 0.85
LABGEO PT10 (Samsung healthcare, Korea) [95]	ALB, ALP, ALT, AST, TBL, glucose, GGT, TP, TC, HDL, TG, CR, amylase, BUN, LDL	10 minutes	CV = -22.8 - 54.0%	r > 0.95
HEMOCHRON® Jr. Signature+ (International Technidyne Corporation, Edison, USA) [96]	INR	Few minutes	CV ≤ 10%	r = 0.92
Proxima™ (Sphere Medical Ltd, Harston, UK) [97]	pH, pCO_2, pO_2, HCO_3^-, BE, K^+, Hct	< 4 minutes	CV = 2.4 - 251%	r = 0.90 - 2.04
VerOFy®& LIAM™ (Oasis Diagnostics® Corporation, Vancouver, USA) [98]	Salivary cortisol	20 minutes	CV = 7%	r = 0.95
INRatio™ (Alere, Hemosense, Milton Keynes, UK) [99]	INR	1 minute	CV = 5%	r = 0.73
TrueHb (Wrig Nanosystems PVT. Ltd, New Delhi, India) [100]	Hb	< 1 minute	CV = 2.2%	r = 0.99
NBM-200 (OrSense ltd, NesZiona, Israel) [101]	Hb	< 1 minute	CV = 4.28%	r = 0.89
FIA8000 (GeTein BioMedical Inc., Portland, USA) [102]	CysC, mAlb, NGAL, ß2-MG, hs-CRP, PCT	10-20 minutes	CV = 1%	r = 0.99
ProTime InRhythm™ System (Accriva Diagnostics, Inc, San Diego, USA) [103, 104]	INR	< 1 minute	CV = 5.1%	r = 0.97

(Table 2) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Spotchem® EL (Elitech-Arkray, Kyoto, Japan) [105]	Sweat Cl-	1 minute	CV < 5%	r = 0.96
Aution® Micro (Menarini Diagnostics, Florence, Italy) [106]	UBG, TB, protein, nitrite, ketones, glucose, pH, specific gravity and leucocytes	1 minute	N/A	r = 0.80
Combur-Test® strips (Roche Diagnostics Ltd., Rotkreuz, Switzerland) [107, 108]	ALB, specific gravity, protein, glucose, leukocytes, nitrites, pH, Hb, ketones, TB, UBG	1 minute	CV = 1.7 - 4.9%	r = 0.92
ICR–001® (Techno Medica Co, Japan) [109]	urinary 8-oxodG	5 minutes	CV < 13%	r = 0.98
Radiometer AQT90 FLEX. PCT assay (Neuilly-Plaisance, France) [110]	PCT	19 minutes	CV < 10%	r = 0.99
EasyTouch® GU (Bioptik Technology, Inc., Jhunan, Taiwan) [111]	serum uric acid	20 seconds	CV = 8.6 - 26.3%	r = 0.27
BeneCheck™ Plus (General Life Biotechnology Co., Ltd., New Taipei City, Taiwan) [111]	serum uric acid	15 seconds	CV= 3.1 - 6.9%	r = 0.71
HumaSens^{plus} (HUMAN, Wiesbaden, Germany) [111]	serum uric acid	15 seconds	CV = 4.5 - 8.0%	r = 0.75
UASure (Apex Biotechnology, Hsinchu, Taiwan) [111]	serum uric acid	30 seconds	CV) 9.5 - 31.2%	r = 0.16
i-Stat (Abbott Laboratories, Abbot Park, IL) [112]	Hb	15 minutes	N/A	r = 0.67
Cobas® b221 (Roche Diagnostics, Belgium) [113]	TCO_2, pO_2, pCO_2, Na^+, K^+, Cl^-, CO-oximetry and metabolites	< 2 minutes	CV = 0.1 - 8%	r = 0.99
FastPack® IP System (Sekisui Diagnostics, LLC, Lexington, USA) [114]	αGST	12 minutes	CV = 7.9 - 14.1%	r = 0.99

(CR = creatinine; hct = hematocrit; TG = triglycerides; hemoglobin = Hb; TC = total cholesterol; HDL = high density lipoprotein; LDL = low density lipoprotein; Lac = lactate; HbA1c = glycated hemoglobin; ALT = Alanine Aminotransferase; AST = Aspartate Aminotransferase**;** FORT = Free Oxygen Radicals test; FORD = Free Oxygen Radicals Defence; MCHC = Mean Corpuscular Hemoglobin Concentration; WBC = white blood cells; PLT = platelets; TP = total protein; ALB = albumin; TCO_2 = Total Carbon dioxide; pO_2 = partial pressure of oxygen; pCO_2 = partial pressure of carbon dioxide; PT = prothrombin time; INR = international normalised ratio; aPTT = activated partial thromboplastin time; Na^+ = sodium; K^+ = potassium; iCa^+ = ionized calcium; HCO_3^- = bicarbonate; CO_2 = carbon dioxide; BEb = base excess of blood; BEecf = extracellular fluid; O_2SAT = oxygen saturation; tHb = total hemoglobin; COHb = carboxyhemoglobin; MetHb = methemoglobin; O_2Hb = oxyhemoglobin; HHb = deoxy-hemoglobin; iMg = ionized magnesium; sO_2 = oxygen saturation; cK^+ = potassium ion concentration; cNa^+ = sodium ion concentration, cCl^- = chloride ion concentration, cCa^{2+} = calcium ion concentration; ctHb = total hemoglobin, FO_2Hb = fractional oxyhemoglobin, FCOHb = fractional carboxyhemoglobin, FMetHb = fractional methemoglobin, FHH = faecal human haemoglobin, FHbF = fetal hemoglobin fraction, ctBil = concentration of total bilirubin in plasma; Li^{2+} = lithium; TCa = total calcium; BUN = blood urea nitrogen; TBL = total bilirubin level; CK = creatine kinase; γ-GT = gamma glutamyl transferase; CRP = c-reactive protein; WBC = white blood cell, RBC = red blood cell; SpHb = total hemoglobin; PCT = procalcitonin; BE = base excess; CysC = Cystatin C; mAlb = microalbumin; NGAL = eutrophil gelatinase associated lipocalin; β2-MG = beta-2 microglobulin, hs-CRP = high-sensitivity CRP*;* UBG = urobilinogen; αGST = Alpha Glutathion S-Transferase)

Table 3. Commercially available POC devices for diabetes management.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
StatStrip® (Nova Biomedical, Waltham, MA, USA) (119-123)	glucose	6 seconds	CV = 5 - 7%	r = 0.99
NovaStatstrip® (Nova Biomedical, Waltham, MA, USA) (124-126)	glucose	< 10 minutes	CV = 3.0 - 4.7%	r = 0.97 - 0.98
Precision Xtra™ (MediSense/Abbott Diabetes Care, Abbott Park, IL) (127, 128)	BHB	10 seconds	CV = 2.4 - 5.9%	r = 0.92
Accu-Chek Inform® II (Roche Diagnostics, Belgium) (129)	glucose	5 seconds	CV = 1.7 - 3.7%	r = 0.99
Precision Xceed Pro blood glucose® (Abbott, USA) (128, 130]	BHB	20 seconds	CV = 2.4 - 5.9%	r = 0.99
Assure Platinum blood glucose monitoring system® (Arkray, USA)	glucose	7 seconds	CV = 1.9 - 4.9%	r = 0.99
HemoCue® Glucose 201+ System (HemoCue®, Sweden) [131 - 133]	glucose	1 minute	CV = 2.52 - 3.66%	r = 0.96
YSI 2300 STAT® Plus (YSI Life Sciences, USA) [134 - 139]	glucose and lactate	45-65 seconds	CV = 3.03%	r = 0.96
Scan SureStep Flexx (LifeScan, Johnson & Johnson Company, USA) [140]	glucose	15 seconds	CV = 1.4 - 4.1%	r = 0.98
NycoCard II (Axis-Shield, Norway) (141-143)	HbA1c	3 minutes	CV = 3.1%	r = 0.93
Accu-chek Advantage II (Roche, Basel, Switzerland) [144, 145]	glucose	5 seconds	CV = 0.07 - 2.5%	r = 0.99
Precision PCx (Abbott, Illinois, USA) [144, 146]	glucose	20 seconds	CV = 3.8 -5.4%	r = 0.96
SureStep Flexx (LifeScan, Malpitas, CA) [147]	glucose	15 seconds	CV = 4.2 - 5.9%	r = 0.68

(Table 3) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
DCA Vantage™ (Siemens Healthcare Diagnostics Inc, Australia) [148 - 150]	Albumin/creatinine, HbA1c, glucose	6 minutes	CV = 1.7 - 3.6%	r = 0.74 - 0.98
FreeStyle Precision Neo (Abbott, Diabetes Care Ltd, UK) [151]	glucose, BHB	5 seconds	CV < 3.5%	r = 0.89
StatStrip® (Nova Biomedical, Waltham, MA, USA) [119 - 123]	glucose	6 seconds	CV = 5 - 7%	r = 0.99
NovaStatstrip® (Nova Biomedical, Waltham, MA, USA) [124 - 126]	glucose	< 10 minutes	CV = 3.0 - 4.7%	r = 0.97 - 0.98
LABGEO PT10 (Samsung Electronics, Suwon, South Korea) [152]	HbA1c	7 minutes	CV = 2.6%	r = 0.99
A1C EZ 2.0 (Biohermes, Wuxi, China) [153]	HbA1c	3 minutes	CV = 1.9 - 2.3%	r = 1.00
DPN-Check (Neurometrix Inc., Waltham, MA) [154]	nerve amplitude potential and sural nerve conduction velocity	2 minutes	CV = 3.6 - 8.8%	r = 0.67
FIA8000 (GeTein BioMedical Inc., Portland, USA) [102]	HbA1c	10-20 minutes	CV = 1%	r = 0.99
FastPack® IP System (Sekisui Diagnostics, LLC, Lexington, USA) [114]	TSH	12 minutes	CV = 4 - 7%	r = 0.97
	vitamin d		CV = 4.7 - 15.1%	r = 0.92
	free T4	7 minutes	CV = 7.2 - 11.5%	r = 0.95
Clini5 (Callegari S.r.l., Parma, Italy) [7]	Glu	10 - 180 seconds	CV = 1.37 - 5.38%	r = 0.75 - 0.99
	HbA1c	5 - 10 minutes		

(BHB = β-hydroxybutyrate; TSH = thyroid stimulating hormone; T4 = Thyroxine, HbA1c = glycated hemoglobin)

Table 4. Commercially available POC devices in cardiology.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
i-Stat® Troponin I (Abbott Point-of-Care, Princeton, NJ) [156, 162]	cTnI	7 minutes	CV = 10%	r = 1.06
Triage Cardio3 Tropinin I (Alere™, U.K) [156, 163, 164]	cTnI	20 minutes	CV = 11 - 16.7%	r = 0.94
Pathfast® (Mitsubishi Chemical Medience Corporation, Tokyo) [156, 163]	cTnI	20 minutes	CV = 3.9 - 6.1%	r = 0.89
AQT90® Flex troponin I (Radiometer Medical ApS, 2700 Bronshoj, Denmark [156, 165, 166]	cTnI	10-20 minutes	CV = 10%	r = 0.90
RAMP® troponin I (Biomedical Corp) [156, 167]	cTnI	20 minutes	CV = 10%	r = 0.98
Cardiac Reader® troponin T (Roche Diagnostics, Vilvoorde, Belgium) [156, 168]	myoglobin and troponin T	14 minutes	CV < 9%	r = 0.89 - 0.91
Stratus® CS troponin I (Siemens Medical Solutions Diagnostics) [156, 162]	cTnI	14 minutes	CV = 10%	r = 0.89
Stratus® CS D-dimer (Siements Diagnostic, Marburg, Germany) [159]	D-dimer	14 minutes	CV = 2.9%	r = 0.90
Rapidpia® (Sekisui Medical Co., Ltd. Tokyo) [169]	BNP	15 minutes	CV = 0.9 - 2.1%	r = 0.93
Shionospot® Reader (Shionigi&Co, Osaka, Japan) [169]	BNP	15 minutes	CV = 0.9 - 2.1%	r = 0.93
Biosite® Triage System (Biosite Diagnostics Inc., USA) [170]	cTnl, CK-MB, myoglobin, and NT-proBNP	15 minutes	CV = 6.1 -15.4	r = 0.86
Cobas h232 (Roche Diagnostics Ltd., Rotkreuz, Switzerland) [171]	NTproBNP	8 - 12 minutes	CV = 5.9 - 13.8%	r = 0.97
FIA8000 (GeTein BioMedical Inc., Portland, USA) [102]	cTnI, NT-proBNP, D-Dimer, CK-MB, NT-proBNP/cTnI, CK-MB/cTnI, CK-MB/cTnI/Myo, hFABP, CK-MB/cTnI/hFAB	10-20 minutes	CV = 1%	r = 0.99
Meritas Troponin I (Trinity Biotech Plc, Co Wicklow, Ireland) [156]	cTnI	15 minutes	CV = 10%	r = 0.98
ARTSENS*Touch* (National Instruments S.r.l., Assago, Italy) [172]	Arterial stiffness	Few seconds	CV = 6.2 - 12.5%	r = 0.89
Multiplate® (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) [173]	platelet function	10 minutes	CV > 2%	r = 0.75-0.89

(cTnI = Cardiac troponin I; hsCRP = high sensitivity c-reactive protein; BNP = B-Type Natriuretic Peptide; NTproBNP = N-terminal pro-B-type natriuretic peptide; CK-MB = **creatine kinase-muscle/brain;** hFABP = heart-type fatty acid binding protein)

2.2.4. Viral Infections

Infectious diseases require an accurate and rapid diagnosis in order to limit the spread of infection. Their management mainly relies on the identification of the cause of the infection and on the initiation of a therapy to control host reaction against infection. In clinical practice, the time required to reach the final diagnosis generally exceeds 24 hours leading to unnecessary sufferings and even deaths. In the last few years, nucleic acid-based testing for infectious diseases have become particularly useful in those situations where fast turnaround times are required and centralized laboratories are overloaded. Moreover, conventional instruments are PCR-based, are limited to well-trained hospital staff and are expensive [174]. In the case of HIV infection, enumeration of CD4 lymphocytes accomplished by POCs is a pivotal diagnostic tool for initiating therapy and monitoring its efficacy, thus decentralizing the laboratories and providing results during the course of the patient visit [175]. Implementation of rapid HIV POCs may improve the prevention of such diseases by increasing testing uptake rates, timely diagnosis and access to treatment, and consequently reducing the further virus transmission (Table **5**).

2.2.5. Bacterial Infections

Among bacterial infections, syphilis is one of the most commonly worldwide occurring infection since it can be sexually and congenitally transmitted, with more than 6 million of new cases yearly [243, 244].

Syphilis diagnosis can be accomplished either on clinical manifestations or on serological assays, also accomplished by POCs, which detect IgM, IgG and IgA antibodies from whole blood, serum or plasma, exploiting immunochromatographic strips. Results are available within 30 minutes and the overall procedure requires minimal equipment and training (Table **6**).

Table 5. Commercially available POC devices for viral infections detection.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
INSTI™ (bioLytical Laboratories, Richmond BC) [176, 177]	HIV-1/2 antibodies	10 minutes	N/A	r = 0.99
MBio™ (MBio Diagnostics, USA) [178]	CD4 count	10 minutes	CV = 8.1%	r = 0.97
VISITECT® (Omega Diagnostics Ltd, Scotland, UK) [179]	CD4 count	40 minutes	CV = 15%	r = 0.98
Alere q 1/2 Detect (Alere Healthcare, Waltham, Massachusetts, USA) [180 - 182]	HIV nucleic acids	56 minutes	CV = 5.58%	r = 0.99
Cobas® Liat® system (Roche Molecular Systems, Pleasanton, USA) [183 - 186]	Influenza A/B nucleic acid	20 minutes	CV = 0.9 - 2.9%	r = 0.98
SAMBA I and II (Diagnostics for the Real World Ltd., Cambridge, UK) [187, 188]	HIV-1 nucleic acid	90 minutes	N/A	r = 0.99
OraQuick *ADVANCE*® (OraSure Technologies, Inc., Bethlehem, USA) [189 - 191]	HIV-1/2 antibodies	20 minutes	N/A	N/A
Dual Path Platform (Chembio Diagnostic Systems, Inc, Medford, NY, USA) [192 - 194]	HIV/HCV Antibody	15 - 25 minutes	CV = 0.47%	N/A
SD Bioline (Standard Diagnostics Yongin, Korea) [195]	anti-HCV antibody	5 minutes	CV = 0%	r = 0.83
Bioeasy® (Bioeasy Diagno´stica, Belo Horizonte, Minas Gerais, Brazil) [196, 197]	anti-HCV antibody	10-15 minutes	N/A	N/A
Hexagon® (Human Diagnostics Worldwide, Wiesbaden, Germany) [198, 199]	anti-HCV antibody	5-20 minutes	N/A	N/A
Genedia® Rapid LF (Green Cross Medical Science, Yongin, Korea) [200]	anti-HCV antibody	20-30 minutes	N/A	r = 0.83
Diagnos® Bi-Dot (Mitra, New Delhi, India) [198]	anti-HCV antibody	3 minutes	CV < 20%	N/A
HCV Spot® (MP Biomedicals, Santa Ana, California, USA) [201]	anti-HCV antibody	2 minutes	N/A	r = 0.93
SM-HCV (SERO-Med, Germany) [202]	anti-HCV antibody	10 minutes	N/A	N/A
Ab rapid test (Tema Ricerca, Italy) [203]	anti-HCV antibody	< 3 minutes	N/A	N/A
Orthopox® Bio Threat Alert assay (Tetracore, USA) [204]	anti-OPV antibody	15 minutes	N/A	N/A
Clearview® Exact Influenza A+B (Alere, USA) [205, 206]	influenza A and B nucleoprotein antigens	15 minutes	N/A	N/A
Directigen® EZ Flu A+B (Becton, Dickinson, & Co. Diagnostics, USA) [207 - 209]	influenza A and B nucleoprotein antigens	15 minutes	CV = 4 - 4.5%	r = 0.78
QuickVue® Influenza A+B (Quidel Corp, USA) [210, 211]	influenza A and B nucleoprotein antigens	10 minutes	N/A	r = 0.81
3M Rapid Detection® Flu A+B (3M, USA) [212]	influenza A and B nucleoprotein antigens	15 minutes	N/A	N/A

(Table 5) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
OSOM® Influenza A&B (Sekisui Chemical Co. Ltd, Japan) [213]	influenza A and B nucleoprotein antigens	10 minutes	N/A	r = 0.95
Influenzatop® (All.Diag, France) [214]	influenza A and B nucleoprotein antigens	10 minutes	N/A	r = 0.78
Actim® Influenza A&B (Medix Biochemica, Finland) [215, 216]	influenza A and B nucleoprotein antigens	10 minutes	N/A	r = 0.81
Influ-A&B Respi-Strip® (Coris BioConcept, Belgium) [216, 217]	influenza A and B nucleoprotein antigens	15 minutes	N/A	r = 0.81
Quick® Ex-Flu/ Quick® S- Influ A/B (Denka Seiken Co Ltd, Japan) [216]	Detection of influenza A and B nucleoprotein antigens	15 minutes	N/A	r = 0.86
Espline® Influenza A&B-N (Fujirebio, Japan) [205]	influenza A and B nucleoprotein antigens	15 minutes	N/A	N/A
Rockeby® Influenza A Antigen (Rockeby, Singapore) [218]	influenza A and B nucleoprotein antigens	15 minutes	N/A	N/A
Merlin® dengue (Merlin, Diagnostika GmbH, Bornheim, Germany) [219]	Dengue virus IgM antibody	10 minutes	N/A	r = 0.79
Dengue Duo® (Standard Diagnostics, South Korea) [220, 221]	Dengue virus IgM antibody	15-20 minutes	CV = 3%	r = 0.86
Biosynex® Immunoquick dengue (Biosynex, France) [219]	Dengue virus IgM antibody	15 minutes	N/A	N/A
Bio-Rad® NS1 antigen strip (Bio-Rad, France) [222]	Dengue virus IgA antibody	< 15 minutes	N/A	r = 0.77
Panbio® Dengue (Inverness, Australia) [222]	Dengue virus IgA antibody	10-20 minutes	N/A	r = 0.66
Pima™ CD4 (Alere Inc, Waltham, MA, USA) [223, 224]	CD4 testing	20 minutes	CV = 4.0 -17%	r = 0.89
Liat™ HIV Quant (Roche Molecular Systems, Inc., Branchburg, USA) [225]	HIV-1 nucleic acid	30 minutes	CV = 1.8 - 2.7%	r = 0.96
GeneXpert® HIV-1 Quant (Cepheid Innovations Pvt. Ltd., USA) [226, 227]	HIV-1 nucleic acid	90 minutes	CV = 3.52 - 4.15%	*r* = 0.88
Xpert® HIV-1 (Cepheid, Sunnyvale, USA) [228]	HIV-1 nucleic acid	90 minutes	CV < 3%	r = 0.96
Dengue DAY 1 Test (J. Mitra & Co., India) [229]	NS1 antigen, IgM and IgG	20 minutes	N/A	N/A
Simplexa HSV1 & 2 Direct kit (DIASORIN MOLECULAR LLC, Cypress, USA) [230, 231]	HSV1 and HSV2 nucleic acids	75 minutes	CV = 1.8 - 3.9%	r = 0.84 - 0.89
ReEBOV Antigen Rapid Test (Autoimmune Technologies, New Orleans, USA) [232, 233]	Ebola virus rVP40 antigen	15–25 minutes	N/A	r = 0.96
Aeonose® (The eNose Company, Zutphen, The Netherlands) [234]	viral infections in acute exacerbations of chronic obstructive pulmonary disease	15 minutes	N/A	r = 0.74
i RSV test (Alere Inc. Waltham, USA) [235]	RSV nucleic acid	13 minutes	N/A	N/A
EBOLA Ag K-SeT (Coris BioConcept, Gembloux, BELGIUM) [236]	Ebola virus VP40 viral matrix protein	15 minutes	N/A	N/A
HIV Combo (Alere Inc. Waltham, USA) [237, 238]	HIV core protein p24	20 minutes	CV = 3.6 - 24.11%	r = 0.98
VIKIA® Rota-Adeno (bioMérieux, Marcy l'Etoile, France) [239]	rotavirus structural protein VP6	10 minutes	CV = 3.6 - 12.5%	r = 0.99
GeneXpert® (Cepheid, Sunnyvale, USA) [240]	MPXV nucleic acid	< 90 minutes	N/A	N/A
FACSPresto (Becton Dickinson Biosciences, NJ, USA) [241, 242]	CD4	120 minutes	CV = 9.79%	r = 0.91

(HIV = Human Immunodeficiency Virus; HCV = Hepatitis C Virus; OPV = orthopoxvirus; NS1 = Nonstructural Protein 1; HSV = Herpes Simplex Virus; RSV = respiratory syncytial virus; MPXV = Monkeypox virus).

Table 6. Commercially available POC devices for bacterial infections detection.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Determine® Syphilis TP (Abbott, Princeton, USA) [245]	*Treponema pallidum* antibody	15 minutes	CV = 2.7 - 6.1%	r = 0.98
SD BioLine® Syphilis Duo (Standard Diagnostics, Inc., Gyeonggi-do, South Korea) [246 - 248]	IgG, IgM, and IgA *Treponema pallidum*	15-20 minutes	N/A	r = 0.85
Syphicheck® (Qualpro Diagnostics, Goa, India) [249]	IgM and IgG class of *Treponema pallidum* specific antibodies	15 minutes	N/A	N/A

(Table 6) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Signify Strep A (Abbott, Princeton, USA) [250]	group A Streptococcus carbohydrate antigen	5 minutes	N/A	r = 0.93
ACCEAVA® Strep A (Inverness Medical Professional Diagnostics, Princeton, USA) [251]	streptococcal A antigen	5 minutes	N/A	r = 0.98
CT/NG Xpert Rapid (Cepheid, Sunnyvale, USA) [252, 253]	*Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA	90 minutes	CV = 2%	N/A
BioStar® (GC OIA, ThermoFisher/BioStar, Boulder, Colorado, USA) [254, 255]	L7/L12 ribosomal protein of *Neisseria gonorrhoeae*	25 - 40 minutes	N/A	N/A
Immunoquick® Malaria (Meridian Healthcare srl, Catania, Italy) [256, 257]	Pf HRP-2 and pan malaria-specific pLDH	15 - 30 minutes	CV = 0.2%	r = 0.93
RAPIRUN®*S. pneumonia* (Otsuka Pharmaceutical Co.,Ltd., Tokyo, Japan) [258, 259]	pneumococcal C-ps	< 25 minutes	N/A	r = 0.77
HELIPROBE® (Kibion AB, Uppsala, Sweden) [260, 261]	^{14}C-Urea	15 minutes	N/A	r = 0.95
Determine™ TB LAM (Alere Inc., Waltham, USA) [262 - 264]	LAM of *Mycobacterium tuberculosis*	25 minutes	N/A	r = 0.68
BinaxNOW® (Alere, USA) [265, 266]	pneumococcal and L. pneumophila serogroup 1 antigens	15 minutes	CV < 25%	r = 0.97
Multiplo™ Rapid (Medmira Inc, Halifax, Nova Scotia, Canada) [234, 267]	IgM and IgG antibodies to recombinant Treponema pallidum antigens (Tp0171 (TpN15), Tp0435 (TpN17) and Tp0574 (TpN47)	3 minutes	CV = 4.8%	N/A
aQcare Chlamydia TRF kit (Medisensor, Inc., Daegu, Korea) [268]	*Chlamydia trachomatis* antigen	15 minutes	N/A	N/A
Chlamydia Rapid Test (Diagnostics for the Real World, Cambridge, UK) [269]	*Chlamydia trachomatis* antigen	30 minutes	N/A	N/A
ACON Chlamydia Rapid Test (ACON Laboratories, San Diego, CA, USA) [270 - 272]	*Chlamydia trachomatis* antigen	30 minutes	N/A	r = 0.64
QuickVue Chlamydia Rapid Test (QuickVue) (Quidel Corporation, San Diego, CA, USA)	*Chlamydia trachomatis* antigen	12 minutes	N/A	N/A
RealStar Filovirus Screen RT-PCR kit 1.0 (altona Diagnostics, Hamburg, Germany) [233]	Filovirus RNA	15 minutes	CV = 1.10 - 1.16%	N/A
TrueNat® Malaria (bigtec Labs, Bangalore, India) [273]	*Plasmodium falciparum* and *Plasmodium vivax* malaria nuceic acids	45 minutes	N/A	N/A
TrueNat MTB™ (Molbio Diagnostics Pvt. Ltd, India) [274]	*Mycobacterium tuberculosis* nuceic acid	35 minutes	N/A	r = 0.96
FilmArray® (BioFire Diagnostics, LLC, Salt Lake City, Utah) [275, 276]	*Chlamydia trachomatis, Neisseria gonorrhoeae, Treponema pallidum, Trichomonas vaginalis, Mycoplasma genitalium, Ureaplasma urealyticum, Haemophilus ducreyi* nuceic acids	60 minutes	CV = 4 - 40%	r = 0.89
Aeonose® (The eNose Company, Zutphen, The Netherlands) [234]	bacterial infections in acute exacerbations of chronic obstructive pulmonary disease	15 minutes	N/A	r = 0.72
VIKIA Malaria Ag Pf/Pan™ (IMACCESS©, Lyon, France) [277]	*Plasmodium falciparum* (HRP-2) and non-*P. falciparum* (aldolase)	20–30 minutes	N/A	N/A
Dual Path Platform (DPP®) (Chembio Diagnostic Systems, Inc., Medford, USA) [278]	*Candida albicans* antigen	20 minutes	N/A	N/A
QuikRead go® Strep A (Orion Diagnostica Oy, Finland) [279]	*Streptococcus pyogenes*	< 7 minutes	N/A	N/A
Circulating Cathodic Antigen Urine Cassette Test (Rapid Medical Diagnostics; Pretoria, South Africa) [280 - 282]	*Schistosoma mansoni*	20 minutes	N/A	r = 0.99
Filariasis Test Strip (Alere, Scarborough, ME) [283]	*Wuchereria bancrofti* circulating filarial antigen	10 minutes	N/A	r = 0.94

(Pf HRP-2 = *Plasmodium falciparum*-specific histidine-rich protein-2; pLDH = pan lactate dehydrogenase; C-ps = capsular polysaccharide; LAM = Lipoarabinomannan; HRP-2 = histidine-rich protein 2).

2.2.6. Fertility and Pregnancy

Infertility phenomenon affects 10–15% of couples and usually male factors account approximately half of the cases. Due to the difficulty in diagnose of male subfertility on the basis of only sperm count, simple diagnostic sperm tests have been marketed to allow men to monitor their sperm concentration, motility but also the testosterone concentration [114, 284]. As to the female counterpart, self-tests of pregnancy are increasing due to women's preferences for confidentiality, accessibility of the test tool and rapid results [285, 286] (Table **7**)

2.2.7. Drug of Abuse

Drug abuse either recreational or in competitive sports is considered a significant social problem worldwide. In the last few years, many tests using alternative specimens for drug analysis have been developed in several formats, ranging dipsticks to cup devices, cards or plastic cassettes. Current POCs are immunoassay-based and can discriminate from one class to multiple classes of drugs, *i.e.*, cannabinoids and cocaine and amphetamines. These provide a line or color when the drug of interest is at or above the defined threshold and can utilize paper, thin-layer, or gas chromatography methods. It is crucial for users to understand the strengths, weaknesses, and limitations of these devices to facilitate accurate interpretation of results in order to avoid false-positive results due to cross-reactivity with foods, over-the-counter preparations or commonly prescribed drugs. This latter condition is exacerbated in the case of POC manufacturers who use misleading nomenclature. Among possible available samples saliva is a good candidate being a noninvasive way to evaluate the presence of a drug (Table **8**).

2.2.8. Cancer

Cancer is considered as the second cause of death in the world, with prostate and breast cancer as the most common type of cancers in men and women, respectively (326). Most of the diagnostics tests are based on ELISA technique but unfortunately provide protein markers levels that correspond to advanced stages of the disease. Thus, cancer biomarkers-based POCs are of fundamental importance to diagnose, monitor but also to provide a prognostic approach and treatment of the disease (Table **9**).

Table 7. Commercially available POC devices for pregnancy and infertitlity.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
SpermCheck® (PrincetonBioMeditech) [287 - 289]	sperm count	10 minutes	CV < 7%	r = 0.99
Clinitest® hCG pregnancy test (Siemens Healthcare GmbH, Erlangen, Germany) [290, 291]	hCG	5 minutes	CV = from < 10% to < 4%	r = 0.99
Triage® PLGF test (Alere, San Diego, USA) [292, 293]	PlGF	15–20 minutes	CV = 12.8 - 13.2%	r = 0.86
Actim Prom® (Alere SAS, Jouy-en Josas, France) [294 - 299]	IGFBP-1	5 minutes	N/A	r = 0.78
ICON 25 Rapid hCG (Beckman Coulter Inc., Brea, USA) [300]	hCG	3 - 5 minutes	N/A	r = 0.99
YO®Home Sperm Test (Medical Electronics Systems) [284]	sperm concentration and motility	30 minutes	CV = 9.4 - 11.2%	r = 0.97
ROM Plus® (Clinical Innovations, Salt Lake City, UT, USA) [295, 301]	AFP, IGFBP-1	20 minutes	N/A	r = 0.97
Amnisure® (QIAGEN Sciences LLC, Germantown, USA) [295, 302]	PAMG-1	10 minutes	N/A	r = 0.80
CLINITEK Status+ Analyzer (Siemens Healthcare GmbH, Erlangen, Germany) [303, 304]	hCG	1 minute	CV = 0.44%	r = 0.99
hCG Combo Cassette (Alere San Diego, Inc., San Diego, USA) [305]	hCG	3-5 minutes	N/A	r = 0.94
ICON 20 hCG (Beckman Coulter, Inc., Brea, USA) [305]	hCG	3-5 minutes	N/A	r = 0.97
OSOM hCG Combo Test (Sekisui Diagnostics, LLC, SanDiego, USA) [305]	hCG	3-5 minutes	N/A	r = 0.86
Sure-Vue Serum/Urine hCG-STAT (Fisher Scientific Company, Waltham, USA) [305]	hCG	3-5 minutes	N/A	r = 0.96
Elecsys® (Roche Diagnostics, Basel, Switzerland) [306]	AMH	18 minutes	CV = 5.61%	r = 0.97
VIDAS® (bioMèrieux, Marcy L'Etoile, France) [306]	AMH	35 minutes	CV = 5.18%	r = 0.97
FastPack® IP System (Sekisui Diagnostics, LLC, Lexington, USA) [114]	hCG	12 minutes	CV = 7.8 - 14.5%	r = 0.99
	testosterone		N/A	N/A
	SHBG	8 minutes	CV = 3.21 - 11.53%	r = 0.98

(hCG = human Chorionic Gonadotropin; IGFBP-1 = insulin-like growth factor binding protein-1; AFP = Alpha-fetoprotein; AMH = Anti-Müllerian Hormone; PAMG-1 = placental alpha-microglobulin-1; PlGF = placental growth factor; SHBG = Sex Hormone Binding Globulin).

Table 8. Commercially available POC devices for drugs of abuse detection.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Syva RapidTest d.a.u. 8 (Siemens Medical Solutions Diagnostics) [307]	cocaine, THC, amphetamines, opioids, PCP	5 - 10 minutes	N/A	r = 0.74
Cozart®RapiScan (Cozart Bioscience, London, UK) [308, 309]	cocaine, benzoylecgonine, ecgonine methyl ester	3 minutes	N/A	r = 0.99
Drugwipe® (Securetec, Ottobrunn, Germany) [310, 311]	benzodiazepine, codeine	5 minutes	CV = 10.8%	r > 0.95
Monitect® Oxycodone (Branan Medical Co. (Irvine, USA) [312]	oxycodone and metabolites	4-8 minutes	N/A	N/A
E-Z Split Key® Cup II (Innovacon Company, San Diego, USA) [313, 314]	amphetamine, BZD, buprenorphine, cocaine, marijuana, methadone, METH, MDMA, oxycodone, and propoxyphene, THC, secobarbital, oxazepam, benzoylecgonine, morphine and nortriptyline	5 minutes	N/A	r > 0.96
Triage® TOX Drug Screen (Alere Healthcare, Waltham, USA) [315 - 317]	paracetamol, amphetamines, METH, barbiturates, benzodiazepines, cocaine, methadone, opioids, PCP, THC, TCAs	15 minutes	N/A	r > 0.93
DDS®2 Mobile Test System (Alere, Waltham, USA) [318 - 321]	amphetamine, benzodiazapines, cocaine, METH, opioids, THC	5 minutes	N/A	r = 0.97
Instant-View® Drug Screen Tests (Alfa Scientific Design; Poway, USA) [322]	METH, amphetamines	7 minutes	N/A	N/A
Roche TesTcup (Roche Diagnostic, Basel, Switzerland) [307]	cocaine, THC, amphetamines, opioids, PCP	4 minutes	N/A	r = 0.73
Casco-Nerl microLINE (CASCO NERL DIAGNOSTICS, Baltimore, USA) [307]	cocaine, THC, amphetamines, opioids, PCP	3-8 minutes	N/A	r = 0.70
Biosite Triage (Alere Healthcare, Waltham, USA) [307]	cocaine, THC, amphetamines, opioids, PCP	13 minutes	N/A	r = 0.67
Syva RapidCup d.a.u. 5 (Siemens Medical Solutions Diagnostics) [307]	cocaine, THC, amphetamines, opioids, PCP	4 minutes	N/A	r = 0.66
Drugwipe 5+® (Securetec, Ottobrunn, Germany) [323, 324]	cocaine and metabolites, THC, amphetamines and amphetamine-type designer drugs, ketamine.	5 minutes	N/A	r > 0.92
DrugWipe 5A (Securetec, Ottobrunn, Germany) [325]	cannabis, amphetamines, cocaine, opioids	10 minutes	CV = 1.7 - 13.1%	r = 0.99

(THC = tetrahydrocannabinol*;* PCP = phencyclidine; MDMA = methylenedioxymethamphetamine; METH = methamphetamine; TCAs = tricyclic antidepressants; BZD = benzodiazepines).

Table 9. Commercially available POC devices for cancer detection.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
HemoCue® WBC DIFF (HemoCue®, Sweden) [327]	WBC	5 minutes	CV = 1 - 13.7%	r > 0.95
PSAwatch (Mediwatch Plc, Rugby, UK) [328]	PSA	10 minutes	N/A	r = 0.88
EZ DETECT™ (Biomerica, Inc., Irvine, USA) [329]	FOB	2 minutes	N/A	r = 0.70
NMP22 BladderChek Test (Matritech, MA, USA) [330, 331]	urine NMP22	30 minutes	N/A	r = 0.82
UBC® rapid test (Concile GmbH, Freiburg/Breisgau, Germany) [332, 333]	CYFRA 8 and 18	10 minutes	N/A	r = 0.77
BTA® stat (Polymedco, Inc., Cortlandt Manor, NY) [334, 335]	CFHRP	5 minutes	N/A	r = 0.85
CancerCheck® PSA (concile GmbH, Freiburg, Germany) [336]	PSA	20 minutes	N/A	r = 0.74
Prevent ID CC (Immundiagnostik AG, Bensheim, Germany) [337, 338]	FOB	10 minutes	N/A	N/A
Quantum Blue® (BÜHLMANN Laboratories AG, Schönenbuch, Switzerland) [339, 340]	calprotectin	12 minutes	CV = 4.6 - 5.9%	r = 0.73
M2-PK™ stool test (ScheBo Biotech AG, Giessen, Germany) [341-343]	Pyruvate kinase isoenzyme	120 minutes	CV = 4.5 - 6.1%	r = 0.96
FastPack® IP System (Sekisui Diagnostics, LLC, Lexington, USA) [114]	PSA	12 minutes	CV = 9.4 - 13.1%	r = 0.97
	free PSA		CV = 11.6 - 13.9	r = 0.97

(WBC = White Blood Cells, PSA = Prostate-Specific Antigen; FOB = Fecal occult blood; NMP22 = nuclear matrix protein 22; CYFRA = cytokeratin fragment; CFHRP = complement factor H–related protein).

Table 10. Commercially available POC devices for genetic disorders detection.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Carestart™ (Access Bio, Somerset, USA) [344-346]	G-6-PDH activity	10 minutes	N/A	r = 0.73
G6PD Assay (Trinity Biotech, St. Louis, USA) [344, 347]	G-6-PDH activity	< 70 minutes	CV = 4.5%	r = 0.98
Sickle SCAN™ test (BioMedomics, Inc., Durham, USA) [348-351]	HbA, HbS, HbC	2 minutes	N/A	r = 0.99
Q3 portable real-time PCR instrument (Thermo Fisher Scientific, Waltham, USA) [352]	ABCB1 3435, CYP2C19*2 and CYPC2C19*17 polymorphisms	30 minutes	N/A	r = 1.00
GeneXpert® (Cepheid, Sunnyvale, USA) [353]	*BCR-ABL* gene fusion in leukemia cells	150 minutes	CV = 41.35%	r = 0.99
Verigene CYP2C19 Nucleic Acid Test (Nanosphere Inc, Northbrook, USA) [354, 355]	CYP2C19 polymorphisms	210 minutes	N/A	r = 1.00
RX CYP2C19 System (Spartan Bioscience Inc., Ottawa, Canada) [355, 356]	CYP2C19 polymorphisms	< 60 minutes	N/A	r = 1.00

(G-6-PDH = Glucose 6-Phosphate Dehydrogenase; HbA = adult normal hemoglobin; HbS = human sickle cell hemoglobin; HbC = human hemoglobin C; CYP2C19 = Cytochrome P450 2C19).

Table 11. Commercially available POC devices in dentistry.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
DK13-PG-001 device kit [359, 360]	*Porphyromonas gingivalis*	15 minutes	N/A	r = 0.86
Sonosite Edge (FUJIFILM SonoSite, Inc., Amsterdam, Netherlands) [361]	Mandible evaluation	Few seconds	N/A	N/A
Oral Chroma (Abimedical, Abilit Corp., Osaka, Japan) [362]	hydrogen sulphide, methyl mercaptan, dimethylsulphide	8 minutes	N/A	N/A

2.2.9. Genetics

Traditional DNA tests are used to detect genotypes related to a heritable disease or phenotype of interest for clinical purposes. These methods generally require days to weeks before results are available, thus limiting the clinical practice in different circumstances, whereas POC, employ sophisticated techniques able to identify variations in the genetic sequence requiring a time ranging from few minutes to few hours (Table **10**).

2.2.10. Dentistry

One of the challenges in dentistry is the rapid management of diseases such as chronic periodontitis, generally caused by *Porphyromonas gingivalis,* the rapid detection of which is important for an effective treatment [357, 358]. In this sense, a novel immunochromatographic device for the rapid detection and quantification of *Porphyromonas gingivalis* in subgingival plaque has been recently developed [359, 360]. Also, ultrasonology has now acquired great relevance in dentistry, particularly in those situations where computed tomography may prove hazardous, such as pediatric patients, where a rapid identification of mandibular fractures may rule out the necessity for operative management [361]. An updated overview of commercially available POC in dentistry is given below (Table **11**).

2.2.11. Ophthalmology

Eye injuries and ocular complications frequently occur in emergency department visits, convenient care appointments or primary care evaluations requiring specific training and expert knowledge of ophthalmic diagnostic equipment, which generally are of high costs and are not portable. This latter feature results in problems in case of serious ocular injuries present outside the ophthalmology office. Seidel Test is conventionally used to evaluate the integrity of the anterior globe in trauma patients and the wound severity in post-operative patients. This test is based on a subjective and not standardized outcome due to the different amount of pressure and technique used by clinicians. Other devices used to aid in the diagnosis of eye injuries include X-ray, computed tomography, ultrasound and magnetic resonance imaging that are expensive and restricted to hospital settings due to their size and cost. The OcuCheck Biosensor™ is considered a valid alternative to the subjective Seidel Test providing an objective, rapid (5 minutes) and reliable result of ascorbic acid concentration within the ocular tear film, as a surrogate biomarker of anterior scleral or corneal wound integrity with a good accuracy degree (r = 0.89) [363].

2.2.12. Ultrasonology

In the last 50 years, ultrasonography has become an integral part in many medicinal fields and ongoing technological advancements led to a rapid diffusion of POC ultrasound devices among medical wards, emergency rooms, intensive care units and outpatient clinics; due to high performance, reduced size and low costs (Table **12**).

2.3. POCs in Veterinary Practice

Feline immunodeficiency virus (FIV) and feline leukaemia virus (FeLV) are the two most common viruses in cats associated with significant morbidity [377]. One of the key challenges of POCT manufacturers is to identify infected cats, and beyond ELISA and other immunochromatographic tests, new in-house tests for FIV and FeLV diagnosis have been

introduced to the market. Besides these two viruses, group A rotaviruses, parvovirus and influenza virus tests have also been successfully used in other species including dogs and horses. Moreover, biochemical parameters of POC devices, such as bilirubin, ketones, creatinine, hemoglobin, glucose, leucocytes, nitrites, specific weight, pH, proteins, urobilinogen, lactate, Ca_i and Mg_i, have been investigated for other species including cow and cattle. The turnaround time of result of veterinary POC devices is generally below 20 minutes with an overall high degree of accuracy, providing the veterinarian with a good chance to clearly diagnose the disease, to the clients the possibility to save money and to the animals to minimize the discomfort and the sample volume required (Table **13**).

Table 12. Commercially available POC devices in ultrasonology.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
Vscan Dual Probe (GE Medical Systems, Milwaukee, Wisconsin) [364-366]	deep vein thrombosis	7 minutes	N/A	r = 0.94
FibroScan (Echosens, Paris, France) [367]	liver disease	10 minutes	CV = 2.4 - 15.8%	r = 0.94
ApneaLink® (ResMed, Sydney, Australia)	pulse oximetry and oronasal flow	12 minutes	N/A	r = 0.67
Mindray M7 (Mindray Bio-Medical Co., Shenzhen, China) [368, 369]	chronic heart failure, pneumonia, asthma, chronic obstructive pulmonary disease, pulmonary thromboembolism, acute renal failure	< 6 minutes	N/A	r = 0.90 - 1.00
Vscan™ (GE Healthcare) [370]	kidney length, hydronephrosis, renal pelvis width, diameter of the largest cyst, presence of ureteral jet signs, prostate volume, post-void bladder volume	7 minutes	N/A	r = 0.07 - 0.81
Vscan™ (GE Healthcare) [371]	heart and inferior vena cava	< 3 minutes	N/A	r = 0.78
Vscan (GE Vingmed Ultrasound, Horten, Norway) [372, 373]	left ventricular global systolic function, regional left ventricular dysfunction, right ventricular global systolic function, left atrial size, aortic calcification and stenosis, aortic regurgitation, mitral regurgitation, tricuspid regurgitation, pericardial effusion, pleural effusion, abdominal aorta, inferior vena cava, kidneys, liver and gallbladder	< 11 minutes	N/A	r = 0.44 - 0.86
Vscan™ (GE Healthcare) [374]	acute dyspnoea	< 10 minutes	N/A	N/A
TEG® 5000 (Haemonetics Inc., Braintree, USA) [375, 376]	thrombelastography	Few minutes	CV ≤ 2.1%	r = 0.93

Table 13. Commercially available POC devices in veterinary.

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
SNAP FIV/FeLV Combo (IDEXX Laboratories, Inc., Westbrook, USA) [378 - 380]	antibodies to p15 and p24 protein of FIV and soluble antigen p27 coreprotein of FeLV	10 minutes	CV = 0.6 - 1.1%	r = 0.81 - 0.98
Witness FeLV/FIV (Zoetis US, Parsippany, USA) [378 - 381]	antibodies to gp40 protein of FIV and soluble antigen p27 coreprotein of FeLV	10 minutes	CV = 0.4 - 1.3%	r = 0.81 - 0.98
Anigen Rapid FIV/FeLV (BioNote, Inc., Hwaseong-si, Korea) [378, 380]	antibodies to p24 and gp40 protein of FIV and soluble antigen p27 coreprotein of FeLV	10 minutes	N/A	r = 0.97
VetScan Feline FeLV/FIV Rapid Test (Abaxis, Inc., Union City, USA) [380, 381]	antibodies to gp40 protein of FIV and soluble antigen p27 coreprotein of FeLV	10 minutes	N/A	r = 0.70
Duo Speed (Bio Veto Test, France) [379]	antibodies to gp40 protein of FIV and soluble antigen p27 coreprotein of FeLV	15 minutes	CV = 1.1 - 1.9%	r = 0.94 - 0.98
Virachek®FIV/FeLV (Zoetis US, Parsippany, USA) [379]	antibodies to gp40 protein of FIV and soluble antigen p27 coreprotein of FeLV	15 minutes	CV = 0.2 - 0.6%	r = 0.86 - 0.98
FASTest® ROTA Strip (MEGACOR, Diagnostk GmbH, Hörbranz, Austria) [382]	equine G3P [12]-I6 and G14P [12]-I2 Group A rotaviruses genotypes	5 minutes	N/A	r = 0.88
Witness Parvo (Synbiot-ics, France [383]	canine parvovirus antigen	5 minutes	CV = 0%	N/A
Snap Parvo (Idexx, Germany) [383]	canine parvovirus antigen	8 minutes	CV = 0%	N/A
SpeedParvo (Bio Veto Test, France) [383]	canine parvovirus antigen and feline panleukopenia virus	5 minutes	CV = 0%	N/A

(Table 13) contd.....

POC NAME	MEASURED PARAMETERS	TEST TIME	IMPRECISION	ACCURACY
FastestParvo Strip (MegaCor, Austria) [383]	canine parvovirus antigen and feline panleukopenia virus	5 minutes	CV = 0%	N/A
SAS Parvo (SA Scientific, USA) [383]	canine parvovirus antigen and feline panleukopenia virus	10 minutes	CV = 0.5%	N/A
InPouch™ TF-Feline medium (Bio-Med Diagnostics, White City, USA) [384]	feline *Tritrichomonas foetus*	15 minutes	N/A	N/A
Lactate Plus (Nova Biomedical, Waltham, MA, USA) [385]	canine cerebrospinal fluid lactate	13 seconds	CV < 15%	r = 0.97
Hemoccult Single Slides (Beckman Coulter, Brea, USA) [386]	feline FOB	6 minutes	N/A	N/A
Keto-Test (Elanco Animal Health, Greenfield, USA) [387]	BHBA in cow milk	< 2 minutes	N/A	N/A
Accutrend Plus (Roche Diagnostics, Mannheim, Germany) [388]	cattle blood L-lactate concentration	1 minute	N/A	r = 0.95
Lactate Pro (Abbott Point of Care, Abbott Laboratories, Chicago , USA) [388]	cattle blood L-lactate concentration	15 seconds	N/A	r = 0.99
i-STAT (Arkray Inc, Kyoto, Japan) [388]	cattle blood L-lactate concentration	2 minutes	N/A	r = 0.99
Lactate Scout (SensLab GmbH, Leipzig, Germany) [388]	cattle blood L-lactate concentration	10 seconds	N/A	r = 0.99
Nova CRT8 analyser (Nova Biomedical, Rödemark, Germany) [389, 390]	feline Ca_i, Mg_i	55 seconds	CV = 0.45 - 2.29%	r = 1.00
Accutrend (Roche Diagnostics, Mannheim, Germany) [391]	canine blood L-lactate concentration	< 3 minutes	CV < 5.3%	r = 0.86
Quick chaser Flu A, B (Mizuho Medy Co., Ltd., Tosu, Japan) [392]	equine influenza virus strain A/equine/Kildare/2/2010 nucleic acid	5-10 minutes	N/A	r = 0.67
ESPLINE INFLUENZA A&B-N (Fujirebio Inc., Malvern, USA) [392]	equine influenza virus strain A/equine/Kildare/2/2010 nucleic acid	15 minutes	N/A	r = 0.27
Prorast Flu (Mitsubishi Chemical Medience Co., Tokyo, Japan) [392]	equine influenza virus strain A/equine/Kildare/2/2010 nucleic acid	10 minutes	N/A	N/A
BD Flu Examan™ (Beckton, Dickinson and Co., Franklin Lakes, USA) [392]	equine influenza virus strain A/equine/Kildare/2/2010 nucleic acid	15 minutes	N/A	r = 0.73
ImmunoAce®Flu (Tauns Laboratories, Inc., Izunokuni, Japan) [392]	equine influenza virus strain A/equine/Kildare/2/2010 nucleic acid	3-8 minutes	N/A	r = 0.67
Clinitek 50 Chemistry Analyzer using Multistix10SGTM/MicroalbustixTM dipsticks (Siemens Healthcare Diagnostics, Inc., Tarrytown, USA) [393]	canine glucose, protein, bilirubin, ketones, pH	5 minutes	N/A	r = 0.62 - 0.96
Oral Chroma (Abimedical, Abilit Corp., Osaka, Japan) [394]	hydrogen sulphide, methyl mercaptan, dimethylsulphide in dogs	8 minutes	N/A	N/A

(FIV = feline immunodeficiency virus; FeLV = feline leukaemia virus; FOB = fecal occult blood; BHBA = β-hydroxybutyrate; Ca_i = ionized; Mg_i = ionized magnesium)

CONCLUSION

POC devices are revolutionizing clinical and veterinary practice providing rapid test results in different clinical settings, located outside the human and veterinary hospital environment such as physician or vet office and pharmacy. POC technology is particularly helpful in the pre-analytical phase, reducing misidentification of patients and specimen, sample handling, transport and storage, but also in the post-analytical phase, limiting excessive turnaround time. The advancements in POCs have generally improved the quality of care, the health outcomes, and the affordability of the tests.

The use of POC by clinical personnel might have a positive impact on health-care by identifying patients at risk who need to be referred to the next level of care for an accurate diagnosis and treatment, involving patients in their own care, addressing therapeutic issues with the patients once the results are obtained and designing the disease management programs based on a POC device. Another key element of POC is connectivity, related to the possibility to link laboratory and hospital information systems with electronic the patient records. With the advent of the POCT1-A2 standard, it has now become possible to improve devices, data concentrators, and clinical information systems' interoperability and communication [395]. Although there are many challenges related to the implementation of POCT1-A2 protocol in a POC, a framework-based approach has been shown to standardize implementation across devices with consequent ease of maintenance and a return on investment for POC vendors.

However, besides the growing need for connectivity of POC, the regulatory pressure for digitalization of all medical records and patient outcomes, led to another critical issue: the cybersecurity of such records. This latter becomes particularly critical among interconnected devices or through external interfaces (*i.e*. USB or Ethernet cables), with possible life-threatening consequences for patients. In fact, FDA imposed a serious vigilance to POC manufacturers in order to minimize the risk of cybersecurity threats by constantly monitoring,

evaluating and updating their devices [396].

Since POC outcomes depend on the operator's expertise, training and routine updating are crucial to reduce errors [397]. Moreover, when used appropriately, POC devices are invaluable tools for patients but also for animal care, offering a rapid delivery of results and also allowing a reduction in costs due to: 1) Decreased facility costs [398], 2) Decreased maintenance costs [398], 3) Decreased waiting time [399], 4) Decreased hospitalization [399], 5) Decreased screening time [399] and 6) Improved home care delivery [398].

Nanotechnology-based devices have revolutionized the concept of accuracy in diagnosis and therapy by integrating nanomaterials and biosensors, thus consequently minimizing costs and time to provide results.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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