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Mass Spectrometry - The Future of In Vitro Diagnostics (IVDs)

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Abstract: ***In Vitro Diagnostics should be swift and accurate to ensure patients do not seek unnecessary treatments, delay in needed treatments or become exposed to inappropriate therapies. IVD laboratories are in urgent need of transition from conventional instruments to modern analytical instruments which gives accurate data in the fastest and easiest way. To address this concern, Mass Spectrometry is the perfect solution as it is the gold standard for accuracy. Liquid chromatography (LC), standalone or by coupling with tandem mass spectrometry (LC-MS/MS) and Gas chromatography with tandem mass spectrometry (GC-MS/MS) is particularly powerful for high-resolution separation, identification and quantitation of hormones, amino acids, fatty acids, proteins and peptides [Table-02] even at very low levels of expression. MS analytical instrument vendors are providing affordable benchtop platforms offering high sensitivity, low detection limits and high specificity, leading to better data than alternative testing methods to support clinicians with confident results.***

Keywords: IVD or IVD's – In Vitro Diagnostic/s, MS – Mass Spectrometry, LC-MS/MS - Liquid chromatography with tandem mass spectrometry, GC-MS/MS - Gas chromatography with tandem mass spectrometry, FP – False Positive, FN – False Negative, MALDI-TOF - Matrix Assisted Laser Desorption Ionization – Time of Flight.

1. Introduction

Existing traditional diagnostics assays have several drawbacks in the process of sample to accurate result, we see variations in the results, between labs using the same assays as well as between different assays; it is difficult to get multitude of data in a single run since multiplexing is not supported in the existing current assays, it is very tough to qualify targets when they are in traces or when challenged by interferences, hence laboratories require biological samples in large volumes for effective screening, and during diagnostics procedures false positive (FP) and false negative (FN) results have serious impacts on patient care. False-positive tests lead to discomfort, costs, and risks from additional diagnostic and therapeutic procedures. False-negative tests lead to a sense of security and delays in seeking medical help when symptoms develop [1]. MS techniques, which is a gold standard for accuracy will ease out FP and FN during diagnostics screening which can have serious impacts on patient care [2]. Along with the accuracy of the result one also as to focus on saving precious biological samples, time and reagent cost.

All these concerns have driven the development of alternative testing methods based on mass spectrometry techniques, which offer higher accuracy and robustness than existing traditional assays.

MS analytical vendors provide affordable benchtop LC-MS / MS and GC-MS / MS platforms. Liquid chromatography and gas chromatography system can be used standalone with LC and GC detectors respectively or when coupled with tandem mass spectrometry to form an LC-MS/MS and GC-MS/MS Instrument system for IVD screening purpose. These stacks are particularly powerful for high-resolution separation, identification and quantitation of diversified biological markers including hormones, amino acids, fatty acids, proteins and peptides, at dynamic range from very low levels to high level of expression from complex biological matrices including plasma, serum, urine, blood cultures, Cerebrospinal fluid and many other specimen derived from human body. These modern instruments offer high sensitivity, low detection limits, high specificity, speed, analyte range, high throughput and multiplexing capabilities coupled with a lower cost per sample and reduced sample volumes leading to better data than alternative testing methods to support clinicians with confident results.

2. Methods

Official sites of leading analytical vendors Waters, SCIEX, Shimadzu, Agilent, Thermo Fisher Scientific, and Bruker were visited to get the list of IVD instruments available for IVD screening purpose along with its analytical performance (Table – 01 and Table - 02).

Waters have Xevo TQ-XS, Xevo TQ-S micro, Xevo TQ-S, Xevo TQD, RenataDXmass spectrometry and ACQUITY UPLC I-Class LC instrument for in vitro diagnostic use. Both LC and MS can be in standalone and coupled to form IVD LCMS (MS Xevo TQ-XS, TQ-s micro, TQS, TQD with ACQUITY UPLC I-Class LC) (Chart – 01).

SCIEX have Topaz ™, Citrine™, 4500MD, 3200MD MS instrument and Jasper™ HPLC System.

Shimadzu have Single Quad LC-MS-2020, Triple Quad LC-MS/MS LCMS-8040, Triple Quad LC-MS/MS LCMS-8050 and Triple Quad LC-MS/MS LCMS-8060 mass spectrometry instrument and CTO-20AC CL. CBM-20A CL, CBM-20Alite CL, DGU-20A5R CL, SPD-M20A CL, LPGE LC-30AD CL, SIL-20ACXR CL, SIL-30AC CL, SIL-30ACMP CL, CTO-30A CL, SPD-M30A CL, LC-20ADXR CL, LC-30AD CL, SIL-20AC CL, SIL-20ACHT CL, SIL-20AHT CL, LC-20AD CL, LC-30AD CL, SPD-20A CL, SPD-20AV CL, FCV-20AH2 CL and FCV-32AH CL liquid chromatography instrument for in vitro diagnostic use in standalone and coupled with IVD MS (2020, 8040, 8050, 8060) Instruments (Chart – 01).

Agilent have 6420 Triple Quadrupole MS, Agilent 6460 Triple Quadrupole MS and K1367, K1330, K1312, K4225 and K1316 LC instrument for in vitro diagnostic use. Both LC and MS can be in standalone and coupled to form IVD LCMS (MS K6420, K6460 with LCK1367, K1330, K1312, K4225 and K1316) (Chart – 01).
Thermo Fisher Scientific have Thermo Scientific™ TSQ Quantis™ MD Series mass spectrometer, Thermo Scientific™ TSQ Altis™ MD Series Mass Spectrometer and

Thermo Scientific™ Vanquish™ MD Single Channel HPLC, Thermo Scientific™ Prelude™ MD Dual Channel HPLC, Thermo Scientific™ Prelude™ LX-4 MD Four-Channel HPLC instrument for in vitro diagnostic use. Both LC and MS can be in standalone and coupled to form IVD LCMS (MS Quantis™, Altis™ with LC Vanquish™, Prelude™ (Chart – 01).

Bruker have MALDI Biotyper® Sirius CA System for screening microorganisms from blood cultures through protein fingerprints (Chart – 01).

This IVD instruments come along with IVD compliant software like Waters MassLynx Mass Spectrometry Software with TargetLynx [3], SCIEX - Analyst® MD Software, MultiQuant™ MD and Cliquid® MD Software [4] and Thermo Fisher Scientific - Thermo Scientific™ TraceFinder™ LDT Software [5] which are easy to use and designed for simple instrument control and fast data processing and reporting for multitude of information obtained from single analysis.

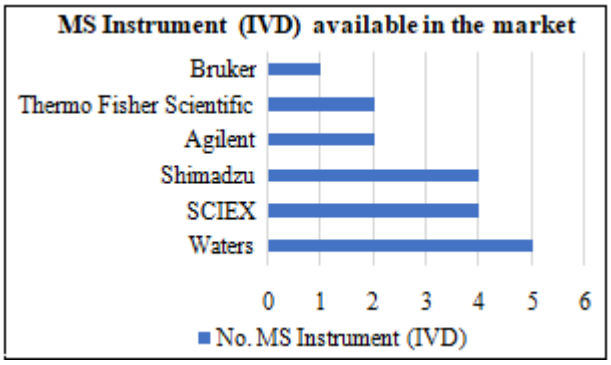

Chart 1: MS Instrument (IVD) available in the market. Waters have released 5 instruments, Bruker -01 instrument and SCIEX and Shimadzu -04 instruments respectively, Agilent and Thermo Fisher Scientific 2 instruments respectively (as of November 2019).

Table 1: Leading MS analytical vendors like Waters, SCIEX, Shimadzu, Agilent, Bruker, and Thermo Fisher Scientific have released powerful MS Instruments that can be used for IVD screening purposes (as of November 2019). Below information are from their respective websites. We need to contact the local instrument representative for the availability of below products for IVD as each country depends on its own local regulatory bodies for approval.

Vendors	Instrument	Comments
Waters	ACQUITY UPLC I-Class / Xevo TQ-XS IVD System https://www.waters.com/waters/en_US/ACQUITY-UPLC-I-Class-Xevo-TQ-XS-IVD-System/nav.htm?locale=en_US&cid=135034342	Ultimate sensitivity and selectivity for the most challenging clinical diagnostic applications [6].
	ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System https://www.waters.com/waters/en_US/ACQUITY-UPLC-I-Class-Xevo-TQ-S-micro-IVD-System/nav.htm?locale=en_US&cid=134873687	A robust and sensitive UPLC/tandem quadrupole MS with compact design, a wide dynamic range and high rates of data acquisition for the clinical laboratory [7].
	RenataDX Screening IVD System https://www.waters.com/waters/en_US/RenataDX-Screening-System/nav.htm?locale=en_US&cid=134986073	The RenataDX Screening System is a fully integrated flow-injection tandem mass spectrometry (FIA-MS/MS) IVD system for high-throughput dried blood spot analysis [8].
	ACQUITY UPLC I-Class / Xevo TQD IVD System https://www.waters.com/waters/en_US/Mass-spectrometer-for-easiest-introduction-of-LC-MS-MS-in-the-clinical-laboratory/nav.htm?locale=en_US&cid=134831492	Designed for routine quantitative LC-MS/MS applications, offering confident quantification and confirmation from challenging samples in the clinical environment [9].
	ACQUITY UPLC I-Class / Xevo TQ-S IVD System https://www.waters.com/waters/en_US/Most-sensitive-mass-spectrometer-for-LC-MS-MS-in-the-clinical-laboratory/nav.htm?locale=en_US&cid=134831529	With patented StepWave technology, our highest-performance instrument provides the highest sensitivity to accurately quantify trace analytes in the most complex of matrices encountered in the clinical laboratory [10]
SCIEX	Topaz ™ LC-MS/MS IVD systems https://sciex.com/products/in-vitro-diagnostics/medical-devices/topaz-system	The Topaz system is the LC-MS/MS solution, clinical labs have been waiting for – simple to learn, adopt and sustain, it sets the new standard for accuracy without the complexity [11].
	Citrine™ MS/MS IVD systems https://sciex.com/products/in-vitro-diagnostics/medical-devices/citrine-system	SCIEX Citrine™ MS/MS system is an in vitro diagnostic medical device that provides you with the highest performance and reliability to tackle today's difficult assays, and the versatility to address tomorrow's challenges [12].
	4500MD LC-MS/MS IVD systems (Triple Quad™ 4500MD System, QTRAP® 4500MD System) https://sciex.com/products/in-vitro-diagnostics/medical-devices/4500md-mass-spectrometer	The SCIEX 4500MD Mass Spectrometry series is a benchtop LC-MS/MS solution that delivers best-in-class reliability, reproducibility and performance for routine clinical testing [13].
	3200MD LC-MS/MS IVD systems (API 3200MD™ System and 3200MD QTRAP® System) https://sciex.com/products/in-vitro-diagnostics/medical-devices/3200md-mass-spectrometer	The 3200MD Mass Spectrometry systems are affordable benchtop clinical LC-MS/MS platforms that deliver exceptional performance and application versatility for clinical laboratories [14].
	Jasper™ HPLC System https://sciex.com/products/in-vitro-diagnostics/medical-devices/jasper-hplc	Designed for use with SCIEX IVD mass spectrometers, the Jasper HPLC system brings the proven performance and reliability of a SCIEX LC-MS/MS solution to your clinical laboratory [15].

Shimadzu	Single Quad LC-MS-2020 CL LC-MS IVD System https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/Corporate/Clinical_Brochure_2017.pdf	An ultra-fast single-quadrupole mass spectrometer (MS) designed for ease of use with an HPLC or UHPLC system [16].
	Triple Quad LC-MS/MS LCMS-8040 CL IVD System https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/Corporate/Clinical_Brochure_2017.pdf	An ultra-fast triple quadrupole mass spectrometer (MS/MS), incorporating improved ion optics systems for increased sensitivity [17].
	Triple Quad LC-MS/MS LCMS-8050 CL IVD System https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/Corporate/Clinical_Brochure_2017.pdf	This high-sensitivity triple quadrupole mass spectrometer (MS/MS) offers outstanding measurement speeds and quantitative performance [18].
	Triple Quad LC-MS/MS LCMS-8060 CL https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/Corporate/Clinical_Brochure_2017.pdf	With new ion focusing technology and incorporating Shimadzu's proprietary ultrafast technologies, the LCMS-8060. CL creates a meaningful impact on trace quantitative detection [19].
	Column Oven (CTO-20AC CL) Communications- CBM-20A CL Communications - CBM-20Alite CL Degassing Unit - DGU-20A5R CL Diode Array Detector - SPD-M20A CL Low Volume - LPGE LC-30AD CL Nexera CL Autosampler - SIL-20ACXR CL Nexera CL Autosampler - SIL-30AC CL Nexera CL Autosampler - SIL-30ACMP CL Nexera CL Column Oven - CTO-30A CL Nexera CL Diode Array Detector - SPD-M30A CL Nexera CL Liquid Chromatograph - LC-20ADXR CL Nexera CL Liquid Chromatograph - LC-30AD CL Prominence CL Autosampler - SIL-20AC CL Prominence CL Autosampler - SIL-20ACHT CL Prominence CL Autosampler - SIL-20AHT CL Prominence CL Liquid Chromatograph -LC-20AD CL Reservoir Switching Valve for LC-30AD CL UV-VIS Detector - SPD-20A CL UV-VIS Detector - SPD-20AV CL Valve Unit - FCV-20AH2 CL Valve Unit - FCV-32AH CL https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/Corporate/Clinical_Brochure_2017.pdf	LC for in vitro diagnostic use in standalone and coupled with IVD MS (2020, 8040, 8050, 8060) Instruments [20].
Agilent	Agilent 6420 Triple Quadrupole LC/MS IVD System https://www.agilent.com/en/promotions/medical-devices	The Agilent 6420 is economical and easy to use – a perfect workhorse instrument for clinical laboratories. The 6420 provides proven sensitivity and reliability with an affordable price for general quantitation applications [21].
	Agilent 6460 Triple Quadrupole LC/MS https://www.agilent.com/en/promotions/medical-devices	The Agilent 6460 adds Agilent Jet Stream technology to dramatically increase sensitivity for a wide range of applications and provides sub femtogram sensitivity for more challenging trace analysis [22]
	1260 Infinity High-Performance Autosampler Clinical Edition (K1367) 1290 Infinity Thermostat Clinical Edition (K1330) 1260 Infinity Binary Pump Clinical Edition (K1312) 1260 Infinity High-Performance Degasser Clinical Edition (K4225) 1260 Infinity Thermostatted Column Compartment Clinical Edition (K1316) https://www.agilent.com/en/promotions/medical-devices	The 1260 Infinity LC Clinical Edition is intended for use with Agilent K6420 or K6460 Class I Medical Device Mass Spectrometers. The 1260 Infinity LC Clinical Edition sets higher standards in quality and value to give you greater confidence as you establish your Lab Developed Test (LDT) [23].
Thermo Fisher Scientific	Thermo Scientific™ TSQ Quantis™ MD Series mass spectrometer IVD system https://www.thermofisher.com/order/catalog/product/TSQ02-21002#/TSQ02-21002	Achieve the sensitivity to perform routine quantitative analyses with remarkable speed and robustness [24].
	Thermo Scientific™ TSQ Altis™ MD Series Mass Spectrometer IVD System https://www.thermofisher.com/order/catalog/product/TSQ02-21001#/TSQ02-21001	The TSQ Altis MD Series mass spectrometer, a Class I medical device, offers superb analytical performance and features the maximum usability, sensitivity, and robustness required for laboratory-developed tests (LDTs) from clinical diagnostic laboratories [25].
	Thermo Scientific™ Vanquish™ MD Single Channel HPLC Thermo Scientific™ Prelude™ MD Dual Channel HPLC Thermo Scientific™ Prelude™ LX-4 MD Four-Channel HPLC https://www.thermofisher.com/in/en/home/products-and-services/promotions/industrial/be-sure.html	The TSQ Altis™ and Quantis™ MD Series triple-stage quadrupole mass spectrometer has been evaluated and determined to be compatible with the mentioned Thermo Scientific LC instruments [26].

Bruker	MALDI Biotyper® Sirius CA System https://www.bruker.com/products/mass-spectrometry-and-separations/fda-cleared-maldi-biotyper-usa/maldi-biotyper-sirius-ca-system.html	The MALDI Biotyper® Sirius CA System is Bruker's newest MALDI Biotyper family member, adopting the user-friendly high capacity vacuum system valued by users of the MALDI Biotyper smart, combined with the power of a 200 Hz smartbeam™ laser and the latest developments in electronics [27].

Table 2: Lists the details of the analytical performance of IVD instruments provided by different MS vendors in quantifying and qualifying variant biomolecules from a divergent human substrate

Instrument Vendors	Analytical performance of
Waters - ACQUITY UPLC I-Class with Xevo TQ-XS IVD System	Testosterone, androstenedione, 17-hydroxyprogesterone, dehydroepiandrosterone sulfate, cortisol, 11-deoxycortisol, and 21-deoxycortisol, 17β-estradiol (E2) and estrone (E1) in serum (2019)[28]. https://www.waters.com/waters/library.htm?locale=en_US&cid=135034342&lid=135035343 Aldosterone in plasma (2019) [29]. https://www.waters.com/waters/library.htm?locale=en_US&cid=135034342&lid=135035339
Waters - ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System	Androgens, Progestogens, and Glucocorticoids [30].https://www.waters.com/waters/library.htm?locale=en_US&cid=134873687&lid=134977894
Waters - ACQUITY I-Class/Xevo TQ-S micro IVD System	Progestogens and Androgens [31].https://www.waters.com/waters/library.htm?locale=en_US&cid=134873687&lid=134987992 Mineralocorticoid [32]. https://www.waters.com/waters/library.htm?locale=en_US&cid=134873687&lid=134987663
Waters - RenataDXIVD Screening System	Amino Acids, Free Carnitines and Acylcarnitines in Dried Blood Spots (2018) [33]. https://www.waters.com/waters/library.htm?locale=en_US&cid=134986073&lid=134999905 Butyl Esters of Amino Acids, Free Carnitine, and Acylcarnitines in Dried Blood Spots[34].https://www.waters.com/waters/library.htm?locale=en_US&cid=134986073&lid=134999878
AB SCIEX - Citrine® MS/MS IVD LCMS System	Free Triiodothyronine and Free Thyroxine (Free T3/T4). 1, 25-Dihydroxyvitamin D3 and D2, Steroids, Water-Soluble Vitamins, and Fat-Soluble Vitamins, 11-nor-9-Carboxy-THC (THC-COOH) in Hair Aldosterone, Total Testosterone, Estrone, Estradiol, and Estriol, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol, 17-Hydroxyprogesterone, and Androstenedione. Simultaneous Analysis of Aldosterone, Estradiol, Estriol, Estrone, Androstenedione, Corticosterone, Cortisol, Cortisone, 11-Deoxycortisol, 21-Deoxycortisol, DHEA, 17-Hydroxyprogesterone, 21-Hydroxyprogesterone, Prednisone, Testosterone, Replicate injections of Aldosterone and Testosterone robustness study and 90+ Drug Compounds in Human Urine [35]. https://sciex.com/Documents/brochures/clinical/clinical-DX-compendium-V2.pdf?elqTrackId=c5381997aa6d4f3ca8e19154f4cad51c&elqaid=1505&elqat=2&_ga=2.48609830.1230945802.1572251237-635947952.1561009013&_gac=1.196089310.1571810003.Cj0KCQjw0brtBRDOARIsANMDykaSXJBKgR3ckKZGROhFza3YeZMLmMM-kGMk9t3jlhK2VtPJteJAe4MaAkdCEALw_wcB
AB SCIEX - Triple Quad™ 4500MD IVD LCMS System	Metanephrine, Normetanephrine, 3-Methoxytyramine, Testosterone, Androstenedione, Cortisone, Cortisol, 11-Deoxycortisol, Corticosterone, 17-Hydroxyprogesterone, DHEA, and Progesterone, Methylmalonic Acid in Serum;Caspofungin, Itraconazole, Hydroxyitraconazole, Voriconazole, and Fluconazole, Methamphetamine, Morphine, Benzoylecgonine, Methadone, Phencyclidine, Amphetamine, and Oxazepam in Oral Fluid; Methamphetamine, Morphine, Benzoylecgonine, Methadone, Phencyclidine, Propoxyphene, and Methaqualone in Urine; Vitamin B1 & B6 in Whole Blood;Cyclosporin A, Tacrolimus, Sirolimus, and Everolimus in whole bloodmatrix [36]. https://sciex.com/Documents/brochures/2019/4500MD-Analytical-Performance-Booklet-Vol2.pdf
Shimadzu - GCMS-TQ8030 IVD System	104 Metabolites Extracted from Human Embryonic Stem Cells Using GC-MS [37]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/GCMS/GCMS-TQ8030%20Application%20-%20Analysis%20of%20Metabolites%20Extracted%20from%20Human%20Embryonic%20Stem%20Cells%20Using%20GC-MS%20%28Japan%29.pdf 3-Hydroxyisovaleric acid-2TMS, Homocysteine-3TMS, Aconitic acid-3TMS, Kynurenine-3TMS analysis of Metabolites in Serum [38]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/GCMS/GCMS-TQ8030%20Application%20-%20Analysis%20of%20Metabolites%20in%20Serum%20Using%20GC-MS_MS%20%28Japan%29.pdf
Shimadzu - GCMS-TQ8040 IVD System	Analysis of Toxicological Substances in Whole Blood Using Smart Forensic Database [39]. https://www.ssi.shimadzu.com/literature/literature2240.html Analysis of Metabolites (124) Extracted from Human Embryonic Stem Cells using GCMS-TQ8040 Application [40]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/GCMS/GCMS-TQ8040%20Application%20-%20Analysis%20of%20Metabolites%20Extracted%20from%20Human%20Embryonic%20Stem%20Cells%20using%20GC-MS_MS%20%28Japan%29.pdf Multicomponent Analysis of Metabolites (221) in Human Plasma using GC-MS_MS [41]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/GCMS/GCMS-TQ8040%20Application%20-

	%20Multicomponent%20Analysis%20of%20Metabolites%20in%20Human%20Plasma%20using%20GC-MS_MS%20%28Japan%29.pdf
LCMS-8030 Triple Quadrupole Mass Spectrometer	Screening of Sulfa Drugs [42]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/lcms/LCMS-8030_8040%20Application%20-%20Screening%20of%20Sulfa%20Drugs%20Using%20the%20LCMS-8030%20Triple%20Quadrupole%20Mass%20Spectrometer%20%28Japan%29.pdf Structural Analysis of 26 Pharmaceutical Compounds [43]. https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/Products/literature/lcms/LCMS-8030_8040%20Application%20-%20Structural%20Analysis%20of%2026%20Pharmaceutical%20Compounds%20Using%20Synchronized%20Survey%20Scan%20Measurement.pdf
MALDI Biotyper® Sirius CA System	Identifying Microorganisms by their Molecular Fingerprint - The MALDI Biotyper identifies microorganisms using MALDI-TOF Mass Spectrometry to determine the unique protein fingerprint of an organism.The reference library comprises spectra from thousands of strains currently, more than 2, 400 species including the common clinical species and also rare microorganisms.Gram-negative, Gram-positive bacteria, Mycobacteria, fungi, and yeast are identified from blood cultures which help in the diagnosis of bacterial, yeast and fungal infections [44].https://www.bruker.com/products/mass-spectrometry-and-separations/ivd-ce-certified-maldi-biotyper/features-benefits.html

3. Conclusion

When detecting and quantifying analytes at ultra-low concentrations or when challenged by interferences, nothing else comes close to mass spectrometry. LC-MS/MS and GC-MS/MS analysis methods are very versatile and can be developed rapidly for the analyte of interest. Numerous targets can be detected and quantified in a single run, saving considerably on precious samples and well as time, labor and reagent cost.

Another inherent advantage of mass spectrometry is that technology allows you to capture a multitude of information within a single analysis. The large dynamic range also allows compounds at low and high concentrations to be detected without additional sample preparation. Together, this means that a large number of analytes can be detected in a single injection, providing a broad panel of results, reducing the pre-analytic steps required and enabling faster time to result.

In the countries where IVD analytical instruments are made available, doctors are now recommending diagnostics labs to use IVD grade MS / LC / GC instrument for screening purposes as it is a gold standard for accurate results and will help doctors in providing a correct medical prescription to the patient at right time.

The benefits for the diagnostics using LC-MS / MS and GC-MS / MS are clear, but the diagnostics laboratories have been slow to adopt, this reluctance to switch technologies may be attributed to a many perception that only mass spectrometry experts could run the instruments and analyze the results, implementing mass spectrometry can be a complicated process, challenging regulatory and financial circumstances like need for investment and cost-effective diagnostics.

Accordingly, instrument providers have taken significant steps to improve the simplicity, ease-of-use, and robustness of LC-MS / MS systems in recent years. These include the introduction of in vitro diagnostic (IVD) analyzers (Table – 01 and 02) and reagents kits. These products are developed specifically to be safe and effective for routine clinical diagnostics laboratories and designed to be simple for non-mass spec experts to use and to bring down costs by delivering accurate, rapid and reliable results.

Table – 02 shows LC-MS / MS and GC-MS / MS instrument are gradually at a good pace replacing existing conventional instruments in immunoassay, toxicology, endocrinology and, clinical microbiological fields and becoming the future of IVD screening. Vendors also provide IVD labeled consumables to extract the sample from any of the human derivatives like the serum, plasma, dried blood spots, blood cultured microbial colonies, cerebrospinal fluids, hair, urine, oral fluid, whole blood matrix, and stem cells. Instruments and methods are fine-tuned to address sensitivity in complex human biological matrices including plasma, serum, oral fluids, cerebrospinal fluids, and urine.

MS analytical vendors have a greater number of versatile instrument with cutting edge technology in their portfolio [45] but only a few instruments have undergone regulatory compliance [chart – 01] and available for IVD screening purpose, there is a serious need for getting many more instruments in to IVD compliance category, by doing this will be enriching the diagnostics data. Also, instrument vendors should come up with adequate screening methods for almost every diagnostic marker and make sure IVD class instruments are made available for screening in every region around the globe by going through the regulatory process.

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vitro-diagnostics/medical-devices/4500md-mass-spectrometer
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