OSNA – Accreditation made simple

Top performance needs perfect support

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Sysmex supports your laboratory accreditation

Laboratory accreditation

In an increasing number of countries, medical laboratories have to undergo accreditation procedures according to the international standard ISO 15189 [1] to demonstrate their technical competence and obtain the formal recognition that the required quality management system is in place. Laboratories are assessed by national organisations such as UKAS in UK, COFRAC in France and DAkkS in Germany.

Where does verification come in?

A prerequisite for a laboratory to become accredited is the verification of its analytical methods. Verification is the provision of objective evidence that a measurement system fulfils the manufacturer's specifications [2] in the exact end-user environment.

The OSNA (RD-210 and LYNOAMP CK19 E) products have been developed intending to meet the requirements of the European Regulation (EU) 2017/746 [3] for in vitro diagnostic medical devices and respective harmonised standards. The OSNA method has been validated and is CE-marked as IVD.

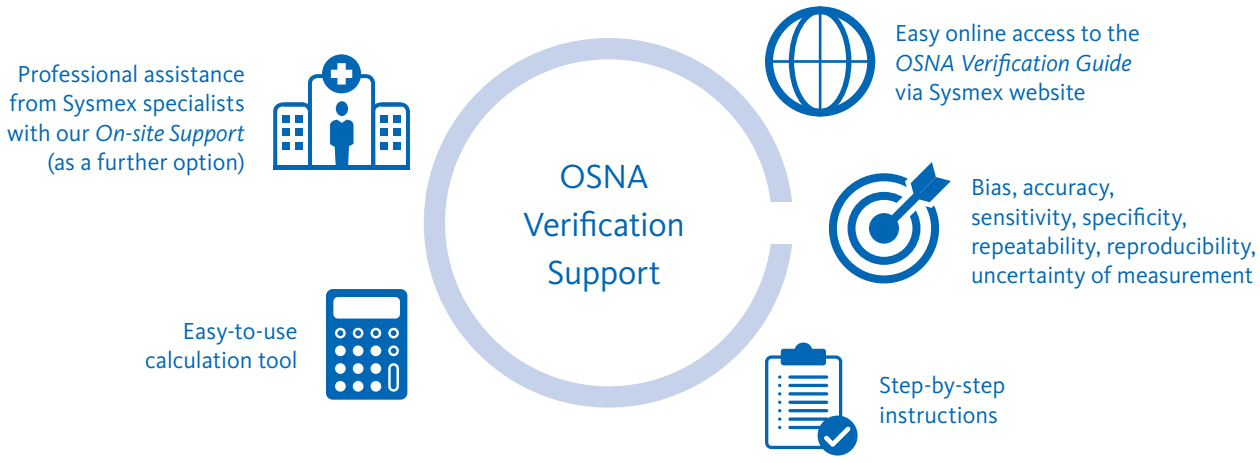
How do you verify OSNA?

With our optional services, Sysmex makes it easy for you.

The *OSNA Verification Guide* proposes detailed protocols on how to prepare and perform eight of the most common analytical performance characteristic tests: accuracy, sensitivity, specificity, bias, repeatability, reproducibility and uncertainty of measurement. The protocols have been designed considering requirements of internationally accepted standards such as CLSI. The complementary calculation tool helps you easily convert the raw data into final reportable results (mean, standard deviation, coefficient of variation).

And should you want more assistance for a trouble-free verification, ask your Sysmex representative about their offers for *On-site Support* where Sysmex specialists will assist you or perform the OSNA verification in your lab.

Your Sysmex representative will be happy to tell you more.



Bibliography

[1] ***ISO 15189*** *(2012): Medical laboratories – Requirements for quality and competence.*

[2] ***JCGM*** *(2012): International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd edition.*

[3] ***REGULATION (EU)*** *(2014): 746 of the EUROPEAN PARLIAMENT and of the COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.*

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