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AMTECH Bulletin. 2024;(1):17-38.
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ISBN 978-5-6051207-3-5

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??????? ?????????, ??? «??????? ???», ??????, ??????, MaslennikovVV1@zdrav.mos.ru, https://orcid.org/0000-0003-2195-3698

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Original article

Functional Characteristics of Medical Devices for In Vitro Diagnostics

Vladimir V. Maslennikov
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Abstract. Functional characteristics of medical devices for in vitro diagnostics (IVD) are described. Systematic approaches to the description of the MD IVD are described. An overview of regulatory documents is presented with a list of MD IVD. Methods of validation and conformity assessment of physical assets are presented

Keywords: medical devices for in vitro diagnostics, IVD, accuracy, precision, repeatability, reproducibility, bias, correctness, blank sample, blank, analytical sensitivity, measuring range, analytical interference, selectivity.
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«?????? ????». ??????? ? ???? ??, ??? ?? ??????????? ?? ????? ? ?? ?????? ?????????????
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(????????????? ? ??????? ???????????????? ????????? ? ????????????? ?????) [3]. ?? ??
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????????????? ???????? ?? ?? ??? ?????? ? ????????? ???? ? ??? 18113-1-2015 [5] (с
01.01.2025 ???????? ? ???? ????? ???????? ???? ? ??? 18113-1-2024 [6]).
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? ????????????? ??????? ?? ?????????? (VIM3-2008), ??????? ? ??????????? ?? ????????
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?????? ????? ?????????? ????????, ??? ???????? ???????? ?????? ?????????? ??????????, ?????? ?????????? ???????????????. ??????? ???????? ???????? ? ???? ????? ???????, ??? ????????? ? ???????????????? ??????. ?????????? ??? ???????????? ???? ?? ????? ??????? ????? ????????? ? ???????????????? ??????????. ?????? ?????? ????????? ?? ?? ??????????. ???????????????? ???????????? ??????????? ??? ?????? ????????. ????????? ???????????? – ??? ?????? ????????????? ??? ???????????? ?????????? [11] [8]. ?????? ??????, ????????? ? GUM, ????????? ??? ???? ???????????, ??? ????? ???????????????? ?????????.

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$$b=x-xref$$ Image not found or type unknown, ???

b- ???????? (?????????? ???????????);

x Image not found or type unknown - ???????? ???????? ? ????? ?????????;

xref Image not found or type unknown - ??????????? ???????? RM (??? ??????? ????????).

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$$b\%=x-xrefxref?100\%$$ Image not found or type unknown, ???

b(%) – ???????? (????????????? ???????????).

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$$R\%=xxref?100\%$$ Image not found or type unknown, ???

R(%) - ??????? ??????????.

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$$R'\%=x'-xrefxspike?100\%$$ Image not found or type unknown, ???

Image not found or type unknown
x' – ??????? ???????? ??????? ??? ???? ? ?????????;
R'(%) – ????????????? ??????? ??????????;
Image not found or type unknown
xspike – ???????? ??????? ? ??????? ? ????????
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Image not found or type unknown
b=x- xref
Image not found or type unknown

b%=x-xrefxref?100%
Image not found or type unknown

R%=xxref ?100%, ???
Image not found or type unknown
xref – ??????? ???????? ??? ????, ?????????? ????????????? ???????.
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???????? ?????????? ???????? [13]. ? ?????????, ??????? ????? ???? ????????? ?? ?????
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??????? ? ??????????? ?????? (L1, L2, L3) ? ??????????? ??????? (H1, H2, H3)
?????????????. ????????? ???????????? ?????, ????????? ?? ???? ???????? ? ???????
????????????? ? ???? ???????? ? ?????? ????????????? (H1, H, H3, L1, L2, L3). ????????
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Image not found or type unknown
???????=L1-L3H3-L3

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?????? ????? ?????????? ????????, ??? ? ????????????? ? ???????????????? ???????? ??????????????, ?? ????????????? ??? ?????? ????????, ? ?????? ???????????? ? ???????????????. ????????? ?????????? (????????, ? ??????? ?????????? ?????? ?? ?????? ?????????) ? ????????? ??????? ????????????? ? ???????????????? ???????? ???? ? ??? 5725-1-2002 [12]. ?????????? ? ????????????? ????????, ????????? ????????????? ??????????????. ????????, ??? ???????, ? ??????? ???????????? ????????????? ????????????? ????????? ???? ??????? ????????????, ?? ??? ??????? ????????????????. ????? ?????????? ????????, ??? ???????????? ??????? ???????????? ??????? ?????, ??? ????????????????. ??? ??????? ??? ?????????? ?????? ?????????? ?????????? ? ???????? ???????????????? ????? ?????????? ????, ?????????? ?????? ???????????? ???????, ?????????? ????????? ? ????? (?????? ?????????, ?? ?????????? ??????? ??? ?????????????). ????? ????????, ??? ????????????? ?????? ?????????? ???????? ??????????? ??? ????????????? ? ????????????????.

???????????? ????????? ?? ???????????? ?????????? ?????????????:

Sr=Sr2, ???

Sr2 – ????????? ?????????????, ????????????? ?? ???????:

Sr2=i=1n(xi-x)2n-1, ???

xi – ???????? i-?? ?????????;

x – ??????? ????????????? ???????? ?????????;

n – ?????????? ?????????.

?? ????????? ???????? ???????????? ?????????? ????????????? ????????????? ?????????? ???????? ?? ???????:

*CV=SrX*100%*, ???

Sr – ??????????? ?????????? ?????????????;

x – ??????? ????????????? ???????? ?????????.

????????????????? ????????? ?? ???????????? ?????????? ???????????????????:

SR=SR2 , ???

SR2 – ????????? ????????????????, ?? ?????? ????? ??????? ?????????? ? ?????? ??? ????????????? ?? ???????:

SR2=Sr2+i=15Si2, ???

Sr2 – ????????? ?????????????;

Si2 (????????? ???????? ?? 1 ?? 5) – ???????? ????????????? ? ???????? ???????????? ????????.

?? ????????? ???????? ???????????? ?????????? ???????????????? ????????????? ?????????? ???????? ???????????????????? ?? ???????:

*CV=SRX*100%*, ???

SR – ???????????? ?????????? ???????????????????;

x – ??????? ?????????? ???????.

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????????????? ????????????? (LoB, LoD, LoQ)

????????? ????????????? ????????????? ????? ????? ??? ????????????? ? ???????????? ?????? ???????? ?? ??????? 1.

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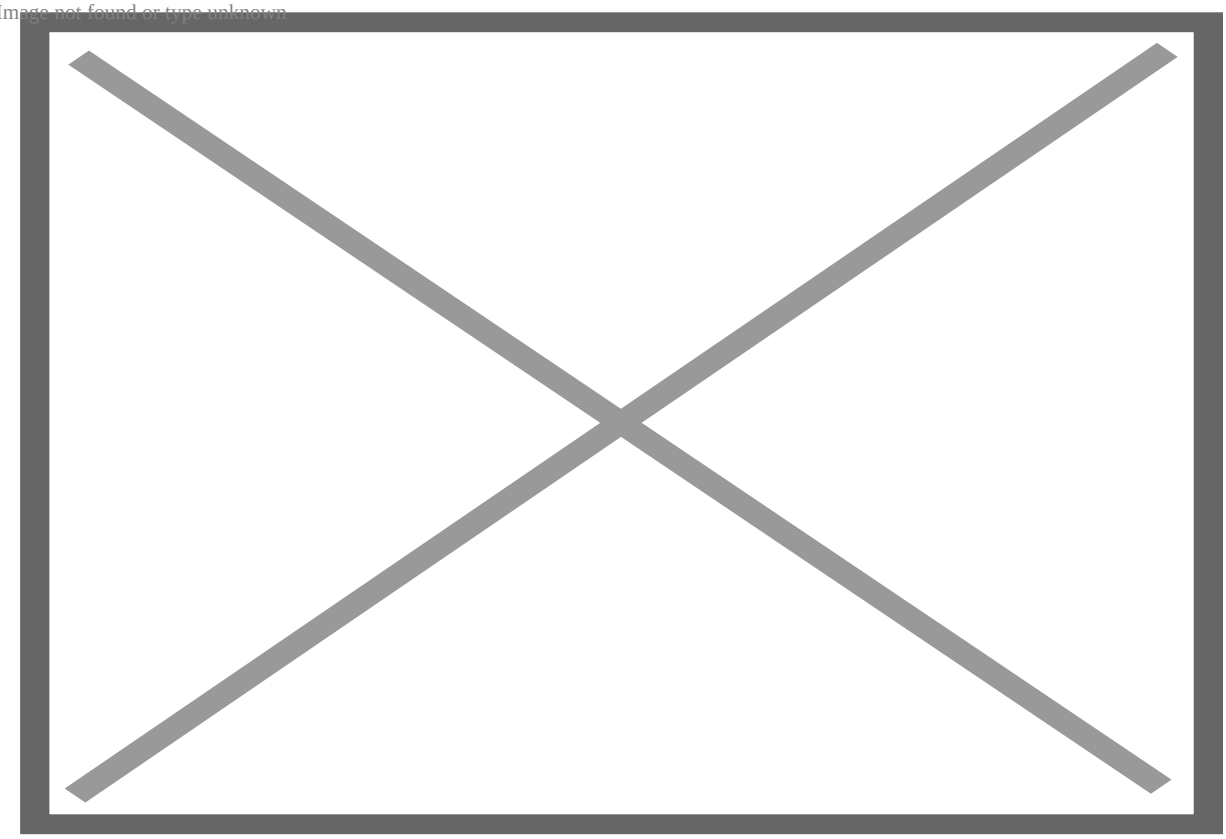

??????? ? 1. ????????? ????????????? ????????????? ????? ????? ??? ????????????? ? ???????????? ??????.

???????? ????? LoB

? ???? ? ??? 18113-1 ???????????? ????????? ?????????? ????????? ???????? ?????.
????????? ???????? ????? (blank indication): ????????? ???????, ???? ??? ????????, ????????? ????, ??? ???????????? ????????????, ?? ??? ???????? ??????? ???????? ????????????? ????????????? ??? ?? ?????????? ? ?????????. (?.3.5 [5]).
???? ?????????? LoB ???????? ??, ?? ????? ?? ????????????? ? ??? ???? ?? ????????????? ?????-???? ??????? ???????????? ??? ?????? ????????????. LoB ???????????? ??? ?????? ????????? ??????? ???????? ?????, ??????? ? ???? ??????? ?????????? ??? ?????? LoD ? ??? ??? ?????????????.
???? ????? LoB ?????????? ? ???????? ??????? ???????, ???? ?????? ????? ???? ???????? ? ???????? ???????????? ?????????? ????????.
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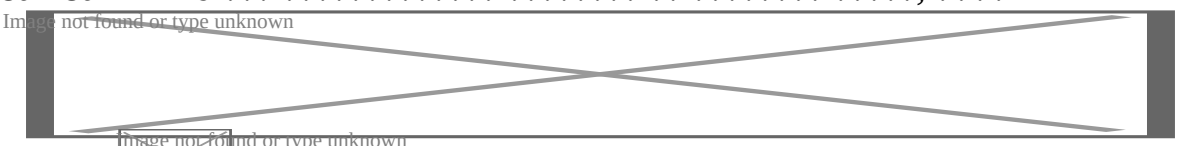
- ???????? ????????;
- ???????? ????? (??????? ??? ???????);
- ??????? ? ?????? ????????? ??????? (????????? ??????? ???????);
- ?????????? ???????? ? ???????? ????????????? (??????????);
- ?????????? ????????? ????????? 6-15 (?????? 10);
- ???????? ???????? ???? ? ???????? ??????? ???????, ???? ? ???????? ???????????? ?????????? ???????? (???? ???? ?? ? ????? ???);

- ???????????? ???????? ???????????? ?????????? *s0′*, ??????? ? ??????????? ????????? ??? ??????? LoD ? LoQ.

? ??????????? ?? ????, ???????????? ?? ??? ??????? *s0′* ???????? ?? ???????? ?????, ?????? ???????? ????????? ???????.

s0′=s01n+1nb ??? ????????????? ???????? ?? ???????? ?????, *????*



s0′=s0n ??? ???????? ?? ???????? ?????, ???

s_0 - ??????????? ?????????? m ????????? ??????????? ? ??????? ????? ??? ?????? ???;

s0′ - ???????????? ??????????, ???????????? ??? ??????? LOD ? LOQ;

n - ?????????? ??????????? ??????????? ????????? ??????????, ??? ?????? ?? ??????? ????????? ??? ???????? ???????? ?????????;

n_b - ?????????? ??????????? ??????????? ?????????? ? ????????? ???????, ?? ??????? ???????????? ???????? ?? ???????? ????? ? ???????????? ? ????????? ????????? [3].

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??? ??????????? ??????? ??????????? ???????? (LoD ????????) ??????? ????????? ?????? ????, ????????? ????? ??? ????????? ?????????, ??? ???? ???????? ?????????? ?????? ???? ?????????? ?? ???? ?? ?????????, ??? ? ?????????? ??????? ??????????? ???? [3].

? ????? ?????? ?????? ??? ?????? LoD ?? ??????????. ?????? ???? ????? ??? ????????????? ?????? ???????????? ????????, ? ??????? ???????? ??????????? ????????? ???????????? ?????????? ????????, ?????? ??????, ?????????? ???????????? ?? ??????? ????. ?????? ?????????? ??????? ?????????? ?=0,05 ? ?????????? t-????????. ?????? ???????????? ??? ???? ?????????? ?? ????????????? ??????? ??????? ?? 10 ???????? ?????, ?????????? ?????????? ???????? ? ???????????? ?????? LoD, ? ???????? ?????.

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?????????? ???????? – 20 ??? ?????? ????????????? ???????????? (? ?????? ????????? ??????????? ?=0,05).

?????? ???????????? ??? ???????? ?=0,05 ????? ???????? ????????? ???????.
??????? ???????? ???? ???????????? ?????????? ???????? ? ?????????? ???????: LoD-20% (0,8LoD), LoD ? LoD+20% (1,2LoD). ????? ???????? ?????????? ?????????? ?????????? ? ?????? ?? 20, 20 ? 3 ???????????? ?????????????.
????????? ???????????? ??? ?=0,05 ???????? ????????? 20 ??? 19 ????????????? ???????????, ?.?. ????????????? ????????? ?????? ???? ??????? ? 95% ??????????.

?????? ????????????? ?????????? (LoQ)

???? ????? ??? LoQ ???????? ?????? ??????? ????????????? ?????????? ????????? ????????. ? ???? ? ??? 18113-1 [5] ??????? ????????.
?????? "?????? ???????????" ?????????? ??? ???????? ?????????? ???????? ????????? ????????, ??????? ???????? ???????????? ????? ?????????? ??? ????????????? ? ??????????? ???????? ?????????????. ?????? ????? ???? ????? ???????? ? ????????? "?????????? ????????????? ????????????".
?????? "?????? ?????????" ?????????? ??? ???????? ?????????? ???????? ????????? ????????, ??????? ???????? ???????????? ????? ???????? ????????????? ? ???????? ???????????????? ?????????. ?????? ????? ????????? ? ????????? "??????? ??????? ???????????" ???????????, "???????? ??????? ????????????? ???????????", "???????? ??????? ?????????" ? ????????????? ???????????????? [5]. ????????? ?????? ?? ????????????? ? ?????????????. ?? ????????, ? ???????????? ? ??????? ?????? ????????????? ?????????, LoQ ????????????, ??? ???????????? ?????????? ????????, ?????????????? ?????????? ???????????? ?????????? (*s0'*) ?? ?????? ??????, ??????????? ?? ???????????? k_Q [3]. ? IUPAC ?? ????????? ???????? k_Q ????????? 10, ? ???? ?????????? ????????? ????????????? ????????? ??? ?????? ?????????????, ???? ?????????? ????????????? ????????????? ???????????? ?????????? (RSD, CV), ??????? 10%. ?????? ???????????? ????????? 5 ? 6, ??? ????????????? CV, ??????? 20 ? 17% ????????????? [3].
??????????? ?? ? ????? ?? ?????????? ?? ???????????? ???????? ?????? ???????????? LoQ ? ????? ????. ?????? ?????? ?? ????????? ?????? ???????????? ???????? ????????? ????? ????????? ????? ?????????? ??????? [15]. ???? ?????? ??????????? ? ???, ??? ????? ????????? ???????? ?????? (?????? ????????? ???????) ? ??????? ?? ????????? ? ??? ???????????? ????????????? ????????? ??? ???????? ? ????????????? ?????? ???????? ???????? ??????, ?.?. ??????? ????????????????? ???? ????????????????????. ????? ???????, ??????? ???????? ?????? ???????????????? ???? ? ? ???? ? ??? ?????????? ???????? ????????? ????????. ?.?. ?????????? ??????? ???????????? ????? ?????? ???? ???????????????? (????????? ? ?????????????).
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???????? ????? ???? ????????? ???, ??? ? ??????????? ????????????, ???????????? ? ???, ???????? ????????, ????????? ????????????, ????????? «???????». ??????? ????? ??, ??? ??? ???????? ???? ??? ???? ?????? ????????? ????????? ?????????? ?????? ????? ? ???? ????????? ? ???, ??? ?????????? ???????? ?????? ??? ?????? ????????????????? ???????.
? ???????? ??????? ?????????? ????????, ????????, ? ?????-?????? ???????????? ????????????, ??????? ?????? ????? ????????????? ? ???????? ????????? ???????? ????????? ????????. ???????????, ??? ???????? ?????????? ???????????? ???????? ?? 10 ?/? ?? 1000 ?/?. ??? ??????????? ?????? ? ??????? ??????? ?????????? ?????????? ????????? ???????? ??????,

?.?. ????????? ?? ?????? ??? ??????? ??????? ?????? ?????????, ????? ????? ???????????
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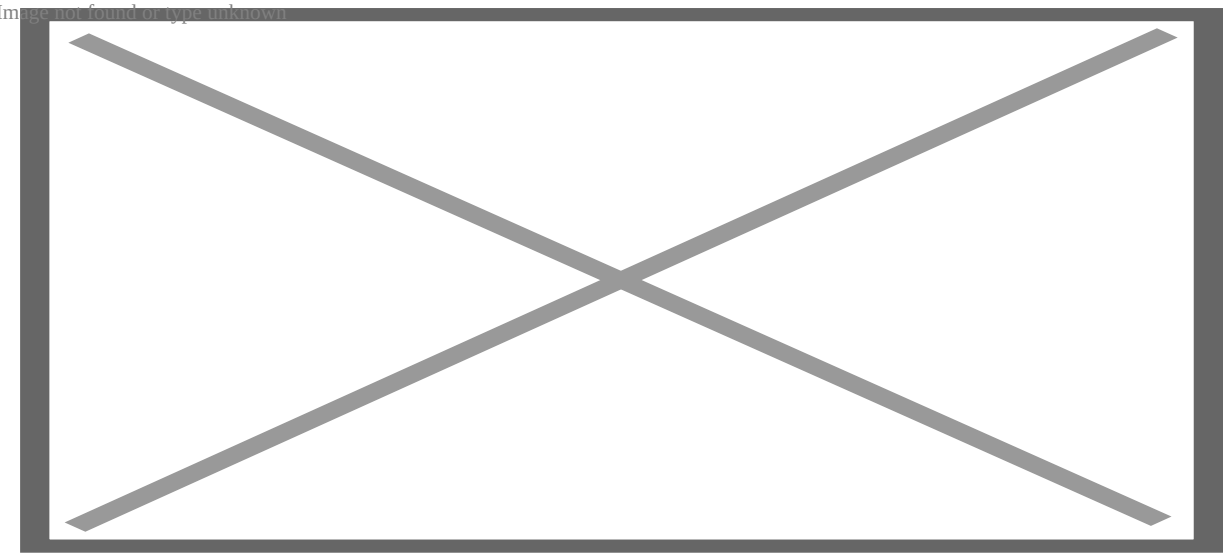

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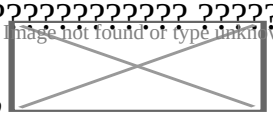

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$?_{?}$ – ????????? (?????????????) ???????? ???????????? ???????? ? ??????????? ?????.
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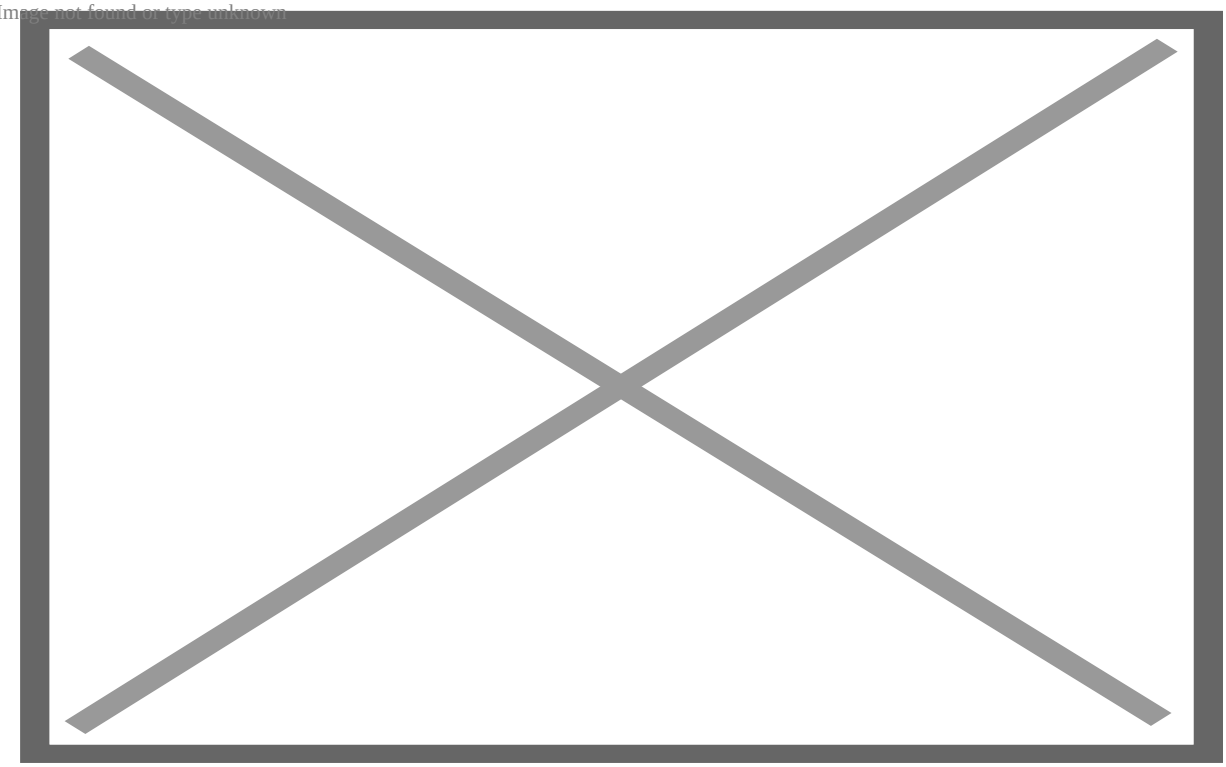
Image not found or type unknown



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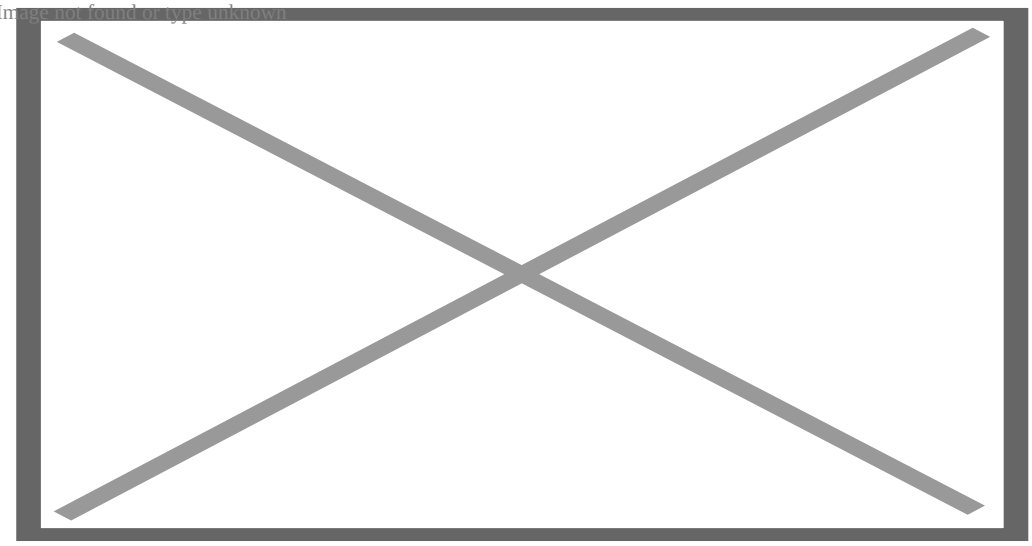

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[1] ???? ? ??? 9000-2015 ??????? ???????????? ????????. ???????? ????????? ? ???????.

[2] ???? ? ???/??? 17000-2022 ?????? ????????????. ??????? ? ????? ????????.

[3] ????????? ????????????? ???????: ???. ? ????. ??. 2-?? ???. ??? ???. ?. ?. ????????????. ????????????? ???????? ???????????????? ? ????????????? ??????????: ???. ? ????. ??. 3-?? ???. ??? ???. ?. ?. ??????. ?????????? ??? ??????????. – ???.: ??? «?????????», 2016. – 312 ?., ??. ISBN 978-5-91884-075-7

[4] ???? 34100.1-2017/ISO/IEC Guide 98-1:2009 ???????????????? ?????????. ????? 1. ???????? ? ?????????? ?? ????????? ???????????????? ?????????.

[5] ???? ? ??? 18113-1-2015 ?????????? ??????? ??? ?????????? in vitro. ??????????, ????????????? ????????????? (??????????). ????? 1. ???????, ?????????? ? ????? ??????????.

[6] ???? ? ??? 18113-1-2024 ?????????? ??????? ??? ?????????? in vitro. ??????????, ????????????? ????????????? (??????????). ????? 1. ???????, ?????????? ? ????? ??????????.

[7] ???? ? 51352-2013 ?????????? ??????? ??? ?????????? ?? ?????. ?????? ?????????.

[8] ??? 29-2013 ???????????? ?? ????????????????? ?????????????. ????????????? ??????? ?????????? ???????? ?????????. ??????????. ???????? ??????? ? ??????????.

[9] ???? ? ??? 3534-1-2019 ????????????? ??????. ??????? ? ???????? ??????????. ????? 1. ????? ????????????? ??????? ? ???????, ???????????? ? ?????? ????????????.

[10] ???? ? ??? 3534-2-2019 ????????????? ??????. ??????? ? ???????? ??????????. ????? 2. ?????????? ??????????.

[11] ????????????? ??????? ?? ??????????: ???????? ? ????? ??????? ? ????????????? ???????: ???. ? ????. ? ??. / ??????. ????.-??????. ??-? ?????????? ??. ?. ?. ??????????, ???????. ???. ??-? ??????????. ???. 2-?, ????. — ???.: ??? «????????????», 2010. — 82 ?. ISBN 978-5-91259-057-3.

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[15] ?????????? ?.?. ????????????? ????????????? ????????? ? ?????? ???????????? ?????????? ??????? ??? in vitro ?????????? // ????????? ?????. 2023. ? 1. ?. 5-15.

[16] NCCLS. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. NCCLS document EP6-A (ISBN 1-56238-498-8). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.
[17] ???? ? ??? 17511-2022 ??????? ??????????? ??? ???????????? in vitro. ?????????? ? ???????????? ??????????????? ???????????????? ????????, ??????????? ????????????, ??????????? ?????????? ???????????? ? ???????? ????????????????? ????????? ????????.

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[5] ISO 18113-1:2009 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1. Terms, definitions and general requirements.
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[7] ???? ? 51352-2013 In vitro diagnostic medical devices. Test methods.
[8] ??? 29-2013 State system for ensuring the uniformity of measurements. Metrology. Basic terms and definitions.
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