**Appendix Table E4. Reporting characteristics and methodological quality of studies of analytic validity**

| **Author****Year****Country****PMID** | **Was the execution of the assay described in sufficient detail to permit replication?** | **Were both positive and negative control samples tested?** | **Were negative control materials from the same** **type of tissue, and collected, stored, and processed in the same way that sample materials used clinically for testing will be?** | **Were the tests performed with positive or negative control samples being blinded to the testers?** | **Were the testing results interpreted with positive or negative control samples being blinded to the interpreters?** | **Were criteria for determining a testing result as positive, negative, indeterminate, or uninterpretable set *a priori*?** | **Was the limit of detection of the test reported?** | **Was the assay linearity range reported?** | **Was the reproducibility of the test when performed multiple times** **on a single specimen established?** | **Was the reproducibility of the test adequately established(across operators/ instruments/reagent lots/ different** **days of the week/ different laboratories)?** | **Were the study data from a multisite collaborative, proficiency testing, or interlaboratory exchange programs?** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Michelson2009{Michelson, 2009 121 /id}USA19435740 | YES | NR | NA | NR | NR | YES(thresholds based on prior literature; criteria for non-evaluable samples) | NO | NO | NO | NO | YES (data read locally at each of the 13 participating centers; centralized testing was done for all samples; agreement between central and local readings NR) |
| Paniccia2009{Paniccia, 2009 127 /id}Italy19461090 | YES | NR | NA | NR | NR | YES(thresholds based on prior literature; alternative thresholds for analytic performance derived from ROC analysis) | NO | NO | YES | NO | NO |
| Oestreich2009{Oestreich, 2009 132 /id}USA19318928 | YES | NR | NA | NR | NR | NO(thresholds for poor response were defined based on the study data: values 2 or more standard errors higher than the mean value for each assay) | NO | NO | NO | NO | NO |
| Marcucci2007{Marcucci, 2007 192 /id}Italy17938810 | YES | NR | NA | NR | NR | NO(thresholds for poor response were defined based on study data on control individuals: values beyond the 90th percentile of controls were considered positive) | NO | NO | NO | NO | NO |
| Frere2007{Frere, 2007 193 /id}France17938809 | YES | NR | NA | NR | NR | NO(thresholds for poor response were defined based on study data on subsequent vascular events, using ROC analysis) | NO | NO | UNCLEAR (COV reported for one of the assays but methods for calculation not reported) | NO | NO |
| Paniccia2007{Paniccia, 2007 198 /id}Italy17723123 | YES | NR | NA | NR | NR | YES (for *some* of the assays cut-offs were derived from the prior literature) | NO | NO | YES (for one of the assays) | NO | NO |
| Van Werkum2006{van Werkum, 2006 209 /id}Netherlands16938130 | YES | NR | NA | NR | NR | NA (no thresholds were employed) | NO | NO | NO | NO | NO |
| Mobley2004{Mobley, 2004 221 /id}USA14969622 | YES | NR | NA | NR | NR | NO | NO | NO | NO | NO | NO |
| Ren2011{Ren, 2011 18276 /id}China21518592 | YES | NR | NA | NR | NR | NO | NO | NO | NO | NO | NO |
| Godino2009{Godino, 2009 18277 /id}Italy19419580 | YES | NR | NA | NR | NR | NO(thresholds were determined based on the observed distribution of measurements) | NO | NO | NO | NO | NO |
| Paniccia2011{Paniccia, 2011 31 /id}Italy21192314 | YES | NR | NA | NR | NR | YES (cut-offs were derived based on prior literature) | NO | NO | YES | NO | NO |
| Koessler2011{Koessler, 2011 32 /id}Germany20873965 | YES | NR | NA | NR | NR | YES(cut-offs in some analyses were those suggested by the manufacturer; other cut-offs were used as part of the study design) | NO | NO | NO(however, experiments were run at least in duplicate and results were averaged) | NO | NO |
| Paniccia2010{Paniccia, 2010 69 /id}Italy20458439 | YES | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | YES | NO | NO |
| Ko2011{Ko, 2011 26 /id}Korea21315223 | YES | NR | NA | NR | NR | NA(no thresholds were used) | NO | NO | NO | NO | NO |
| Aradi2010{Aradi, 2010 60 /id}Hungary20642320 | YES | NR | YES | NR | NR | YES(based on literature for PRI VASP; ROC analyses for LAT) | NO | NO | NO | NO | NO |
| Woo2010{Woo, 2010 61 /id}Korea20890076 | YES | NR | NA | NR | NR | YES(based on prior literature for all assays) | NO | NO | NO | NO | NO |
| Madsen2010{Madsen, 2010 79 /id}Canada20224050 | YES | NR | NA | NR | NR | YES(cut-offs based on prior literature) | NO | NO | YES(for LTA duplicate measurements were obtained and the mean used in analyses; the variance in repeat testing was also reported) | NO(repeat measurements only for one of the tests of interest; details about reproducibility assessment not reported) | NO |
| Siller-Matula2010{Siller-Matula, 2010 89 /id}Austria19943879 | YES | NR | NA | NR | NR | NO(cut-offs were determined based on observed data, using ROC analysis) | NO | NO | NO(however references were provided to previous investigations, some from the same investigators) | NO | NO |
| Cuisset2010{Cuisset, 2010 93 /id}France20142119 | YES | NR | NA | NR | NR | YES(main analyses used cut-offs obtained from prior literature; analyses with alternative thresholds were also presented) | NO | NO | NO(references to previous investigations on reproducibility are provided) | NO | NO |
| Smit2009{Smit, 2009 137 /id}Netherlands19200163 | YES | NR | NA | NR | NR | NO(no explicit thresholds were used) | NO(however, the authors commented that the iron-based assay could obtain measurement beyond the detection limit of other assays used in the study) | NO | YES(duplicate measurements were performed in 111 samples for one of the assays) | NO | NO |
| Gremmel2009{Gremmel, 2009 138 /id}Austria19190818 | YES | NR | NA | NR | NR | NO (thresholds were determined based on the empirical distribution of the results in the study) | NO | NO | NO | NO | NO |
| Schafer2008{Schafer, 2008 158 /id}Germany18841284 | YES | NR | NA | NR | NR | YES(thresholds were based on prior literature) | NO | NO | NO(measures of variability were obtained from a population not on clopidogrel treatment) | NO | NO |
| Shenkman2008{Shenkman, 2008 166 /id}Israel18155752 | YES | NR | NA | NR | NR | YES(cut-offs for the reference standard test were ) | NO | NO | NO | NO | NO |
| Lordkipanidze2008{Lordkipanidze, 2008 170 /id}Canada18520610 | YES | NR | NA | NR | NR | NA(no explicit thresholds were used) | NO | NO | NO | NO | NO |
| Lordkipanidze2009{Lordkipanidze, 2009 108 /id}Canada19840560 | YES | NR | NA | NR | NR | NO(thresholds were determined based on the observed distribution of measurements; positive tests were defined as those > mean + 2\*SD) | NO | NO | NO | NO | NO |
| Lordkipanidze2009{Lordkipanidze, 2009 110 /id}Canada19419755 | YES | NR | NA | NR | NR | NO(no thresholds were used in analyses relevant to analytic validity) | NO | NO | YES(analyses of intra-assay variability were reported) | NO | NO |
| Collet2008{Collet, 2008 160 /id}France18765393 | YES | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | NO | NO | NO |
| Von Beckerath2010{Von, 2010 98 /id}Germany19823079 | YES | NR | NA | NR | NR | NO(thresholds were determined based on the observed distribution of measurements) | NO | NO | NO | NO | NO |
| Varenhorst2009{Varenhorst, 2009 18261 /id}Sweden19249429 | YES | NR | NA | NR | NR | NO(thresholds were determined based on the observed distribution of measurements) | NO | NO | NO | NO | NO(however, two laboratories participated in the study and the authors reported that flow cytometers were “synchronized”) |
| Lordkipanidze2008{Lordkipanidze, 2008 18262 /id}Canada18826988 | YES | NR | NA | NR | NR | YES(based on published guidelines) | NO | NO | NO | NO | NO |
| Jeong2008{Jeong, 2008 18263 /id}S. Korea18617479 | NO | NR | NA | NR | NR | NO(thresholds were determined based on the observed distribution of measurements) | NO | NO | NO | NO | NO |
| Kim2010{Kim, 2010 18264 /id}S. Korea20449634 | YES | NR | NA | NR | NR | YES(for some analyses thresholds were determined based on prior literature; analyses with alternative thresholds were also presented) | NO | NO | NO | NO | NO |
| Lordkipanidze2009{Lordkipanidze, 2009 18265 /id}Canada19250657 | YES | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | NO | NO | NO |
| Pettersen2011{Pettersen, 2011 18266 /id}Norway21426546 | YES | NR | NA | NR | NR | YES(determined based on an independent group of patients receiving aspirin only) | NO | NO | NO | NO | NO |
| Sibbing2008{Sibbing, 2008 18267 /id}Germany18217143 | YES | YES(mentions the use of control samples for quality control) | NR | NR | NR | NO(thresholds were determined based on the observed distribution of measurements) | NO | NO | YES(assessed assay variability) | NO | NO |
| Gaglia2011{Gaglia, 2011 18268 /id}USA21919956 | YWA | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | NO | NO | NO |
| McGlasson2011{McGlasson, 2011 18269 /id}USA21799401 | YES | NR | NA | NR | NR | UNCLEAR(criteria were developed locally by “in house method validations”) | NO | NO | NO | NO | NO |
| Park2012{Park, 2012 18270 /id}Korea21942752 | YES | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | NO | NO | NO |
| Zhang2012{Zhang, 2012 18271 /id}Korea22774770 | YES | NR | NA | NR | NR | YES(based on prior literature) | NO | NO | NO | NO | NO |
| Tsantes2012{Tsantes, 2012 18272 /id}Greece22646492 | YES | NR | NA | NR | NR | YES(based on prior literature and manufacturer information) | NO | NO | YES | NO | NO |
| Liang2012{Liang, 2012 18273 /id}Canada22797934 | YES | NR | NA | NR | NR | NA(no cut-offs were used) | NO | NO | NO | NO | NO |
| Jang2012{Jang, 2012 18275 /id}Korea22811359 | YES | NR | NA | NR | NR | YES(based on prior literature or manufacturer information) | NO | NO | NO | NO | NO |

NA = not applicable; NR = not reported; PMID = PubMed identification number; ROC = receiver operating characteristic.