ROLE OF ANALYTICAL INTERFERENCES IN IN-VITRO DIAGNOSTICS – ANALYSIS OF FIELD SAFETY NOTICES PUBLISHED BY THE BFARM IN GERMANY PUBLISHED 2015-2018

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Introduction: IVD tests are essential in diagnostics, but analytical interferences affect the results. The European Directive 98/79/EC on In-vitro Diagnostics (IVD) regulates marketing and post market surveillance of IVD in the European Economic Area. In cases of incidents and field safety corrective actions (FSCA) manufacturers have to inform the responsible Competent Authority (D: BfArM) and the public by field safety notices (FSN). In Germany FSCA and FSN are published on the BfArM homepage (http://www.bfarm.de/DE/Medizinprodukte/riskinfo/kundeninfo/functions/kundeninfo-node.html). We evaluated FSCA/FSN for IVD regarding interferences by drugs or nutritional supplements. Methods: Analysis was made for FSCA/FSN for IVD published between begin 2015 and end July 2018. Other interferences, e. g. by sample additives were not included. Results: Since late 2004 2538 FSCA were published, of these 817 FSCA within the observation period, including the 43 analyzed interferences. Of these 7 were published for biotin (low concentrated analytes, e. g. thyroid hormones, proteins (e. g. TnI), drugs (e. g. cyclosporine)) causing positive/negative bias, 8 for fulvestrant causing positive bias for estrogen, 38 (multiple entries) for interferences affecting the Trinder reaction (e. g. creatinine) (acetylcysteine (10), sulfasalazin/sulfapyridin (10), acetaminophen (8), metamizol (10)) causing negative bias and 10 others (e. g. opiates, DHEAS, deferoxamin). Conclusions: Drug interferences are a relevant problem in laboratory diagnostics. Causes are different, e. g. interference with the redox reaction (Trinder), the immunological detection (streptavidin-biotin) and immunological cross-reactivity (fulvestrant). Some bear a major risk for patient treatment, e. g. TnI, cyclosporine and fulvestrant. Therefore, potential drug interferences should be considered in diagnostics.