

PROJECT REVIEW

“Detection criteria of EPO-Fc for TD2014EPO”

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Chapter S2 of WADA's Prohibited List 2018 (“Peptide hormones, growth factors, related substances, and mimetics”) lists EPO-Fc under sub-chapter 1.1 (“Erythropoietin-Receptor Agonists”). The current version of WADA's technical document on ESA-analytics (TD2014EPO) describes general criteria of positivity for ESAs (e.g. rEPO, NESP, CERA). Since EPO-Fc cannot be directly detected by IEF-PAGE, SDS- or SAR-PAGE has to be used. However, chapter 2.1.2.4 “EPO-Fc” of the technical document does not define detailed criteria. The reason is that no data from human administration studies of EPO-Fc exist. Hence, it is unclear if both bands, which are typically observed for the standard (the strong band of the monomer AND the weak band of the dimer), have to be present for an adverse analytical finding.

So far, no approved EPO-Fc pharmaceuticals are available. Hence, administration of EPO-Fc to human test persons will be ethically not justifiable. For that reason we plan a study with rats. The test animals will receive EPO-Fc at a dosage, which can be still clearly detected after 48 hours in serum (160 µg/kg) according to literature. Subsequently, serum and urine will be collected and tested for EPO-Fc by SAR- or SDS-PAGE. The study will help to clarify if (1) both bands of EPO-Fc are still observable after 48 hours of circulation in blood, and (2) EPO-Fc can also be detected in urine. Based on these results, more precise criteria for EPO-Fc might be specified in TD2014EPO.