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GLOBAL COMPARATIVE ANTITHROMBIN-FIELD STUDY: IMPACT OF LABORATORY ASSAY VARIABILITY ON THE ASSESSMENT OF ANTITHROMBIN ACTIVITY MEASUREMENT

E Seth-Chhabra^a, A Sadeghi-Khomami^b, Mingjie-Liu^c, Guy-Young^d, S W-Pipe^e, MC Ozelo^f, C Le-Camus^a, M Toh^g, SA Lima-Montalvao^f, Marek-Demissie^a

^a Sanofi, Cambridge, United States

^b Precision BioLogic, Dartmouth, Canada

^c Sanofi, Bridgewater, United States

^d Children's Hospital Los Angeles, Los Angeles, United States

^e University of Michigan, Ann Arbor, United States

^f Centro de Hematologia e Hemoterapia (Hemocentro), Universidade Estadual de Campinas (UNICAMP), Campinas, Brazil

^g Sanofi, France

Objectives: Fitusiran is an investigational, subcutaneous small interfering RNA therapeutic in development for hemophilia A and B, with and without inhibitors that aims to rebalance hemostasis by targeting antithrombin (AT) mRNA to lower AT levels and restore sufficient thrombin generation. To further enhance the benefit-risk profile of fitusiran, the revised AT-based dosing regimen was designed to target AT activity levels of 15–35%. The objective of this study was to evaluate and compare AT activity measurements in hemostasis laboratories using commercially available *in vitro* diagnostic AT activity assays across countries. **Material and methods:** AT immunodepleted and normal pooled plasma were mixed to generate 100%, 36%, 14% and 9% (IU/dL) AT activity levels, based on the Siemens Innovance[®] AT activity assay. Forty-eight Hemostasis Laboratories in 16 countries, blinded to AT activity levels, tested plasma samples in triplicates on three different days. Labs used their routine chromogenic AT activity assays, which evaluate the effectiveness of AT in inhibiting human or bovine factor IIa or Xa. Pre-defined acceptable recovery criteria was set at $\pm 20\%$ of assigned value with intra-assay coefficient of variation (CV) $< 20\%$. **Results and discussion:** Siemens Innovance[®] AT (human FXa based) assay can reliably measure antithrombin across all activity levels (CV 20%) with the highest reproducibility at 14% and 36% (CV 10%). Siemens Berichrom[®] and STA[®] -Stachrom[®] (bovine IIa based) assays could reliably measure 100% and 36% samples but showed lab-to-lab variability for $\leq 15\%$ AT activity. Siemens Berichrom[®] had a CV $> 20\%$ for 14% and 9% samples. For Stachrom[®], only 8/12 labs reported a value for the 14% sample and all labs failed to measure the 9% sample. The

HemosIL[®] (bovine FXa based) assay significantly underestimated AT activity levels $\leq 36\%$. Most labs using HemosIL[®] failed to report any values for 14% and 9% AT samples. Clear inference regarding rarely used AT assays (each $N < 4$) could not be made. **Conclusion:** This study provides important data regarding the performance of commercially available, regulatory cleared AT activity assays across a range of AT activity levels. Siemens Innovance[®] AT (human FXa) assay can reliably measure AT activity at clinical decision points of 15%–35% (CV 10%) and is recommended for fitusiran monitoring. This assay was used for all fitusiran phase 1,2,3 clinical trials for measuring AT activity. Berichrom[®] and Stachrom[®] (bovine FIIa) assays can only be used for fitusiran monitoring after extra validation for $\leq 15\%$ AT (CV $< 20\%$). HemosIL[®] (bovine FXa) assay significantly underestimates AT activity $\leq 36\%$ and should not be recommended for fitusiran patient management.

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AVALIAÇÃO DE ANEMIA E FERROPENIA EM CRIANÇAS DE PRIMEIRO ANO DE ESCOLAS PÚBLICAS

ACM Ciceri^{a,b}, LB Pasqualoto^{a,c}, SA Oliveira^{a,c}, CF Dutra^{a,c}, NC Hoppe^{a,c}, M Roehrs^{a,d}, ISO Tioda^{a,c}, M Kaefer^{a,b,d}, JAM Carvalho^{a,b}, C Paniz^{a,b}

^a Laboratório de Pesquisas em Análises Clínicas Aplicadas (LAPACA), Departamento de Análises Clínicas e Toxicológicas, Universidade Federal de Santa Maria (UFSM), Santa Maria, RS, Brasil

^b Programa de Pós-graduação em Ciências Farmacêuticas, Universidade Federal de Santa Maria (UFSM), Santa Maria, RS, Brasil

^c Curso de Farmácia, Universidade Federal de Santa Maria (UFSM), Santa Maria, RS, Brasil

^d Hospital Universitário de Santa Maria (HUSM), Universidade Federal de Santa Maria (UFSM), Santa Maria, RS, Brasil

Objetivos: A anemia ferropriva é uma doença caracterizada principalmente pela deficiência de ferro no sangue e diminuição das concentrações de hemoglobina. É considerada a mais comum das anemias. A diminuição da quantidade de ferro, pode ser causada por carência nutricional, hemorragias, parasitoses, entre outros. Além disso, existem estudos que relacionam uma diminuição no desenvolvimento cognitivo e motor em crianças que apresentam ferropenia. O objetivo desse estudo foi avaliar a frequência de anemia e ferropenia em crianças de primeiro ano de escolas públicas. **Materiais e métodos:** Foram incluídos 153 alunos de primeiro ano do ensino fundamental, de ambos os sexos, com idade entre 6 e 8 anos, de 6 escolas públicas municipais de Santa Maria/RS. Foram coletadas amostras de sangue em jejum para as análises do hemograma e status do ferro. **Resultados:** Trinta e