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Operational performance evaluation of two Tests for Free Light Chain in Serum

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Background and Objective

Good laboratory quality and performance are critical in managing analysis costs. Performance assessment is an important tool to evaluate all steps and components of the analysis – i.e. han-dling, reagents, run, rerun and maintenance – and concurrently allow to improve performance too. Performance of free light chain (FLC) assays is unknown. To compare the performance of FCL assays in serum we performed an operational evaluation of two different tests.

Methods

Analysis of Kappa and Lambda FLC of non-selected samples were performed in parallel using Freelite on the Optilite (The Binding Site) and SEBIA FLC (Sebia) on the Dynex Agility platform. Performance was assessed measuring all steps of the analysis in the routine diagnostic. Activities were defined at refill (reagent, wash solution, diluent, consumables), call and quality controls (handling, testing, validation), daily maintenance (waste, wash, refill bulk solutions, cleaning), sample (handling, loading, unloading, storage) and resulting (not included in the analysis). Hands-on time (HT) was defined for preparation before starting. Total lead time (TLT) was defined as run preparation, run testing and end-phase.

Results

HT for all activities on Optilite and on Dynex Agility platform was similar (HT: 29 min. for both essays). For a similar number of samples analyzed pro run (n=50 on Dynex Agility and n=54 on Optilite), the TLT was significantly shorter for FLC on Optilite than on Dynex Agility (TLT: 136 min and 150 min, respectively; difference 24 min). Based on 2959 samples that have been test-ed in parallel on each method, re-run and dilution were significantly lower for Sebia (6.8% and 16.2% respectively).

Conclusion

Sebia ELISA assay needs longer TLT but requires fewer dilutions, i.e. lower lab workload and reagent costs. Sebia platform may have lower costs per test and offer better workflow integration in routine labs. Microplate format for batch testing may perfectly fit to handle large volume testing needs.

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