Biotin Pharmacokinetics Study

Fact sheet

About our study

Roche have conducted a study to provide valuable information and clarity about biotin pharmacokinetics.

The results, published in the *International Journal of Pharmacokinetics*, confirm 100% of subjects in the study taking 5 mg of biotin per day are below a tolerance threshold of 30 ng/mL within 3.5 hours.

In addition, 100% of subjects in the study taking 10 mg of biotin per day are below a tolerance threshold of 30 ng/mL within 8 hours.

These data are consistent with the information in our Package Inserts and provide guidance on biotin washout periods necessary to avoid false assay results.

Context

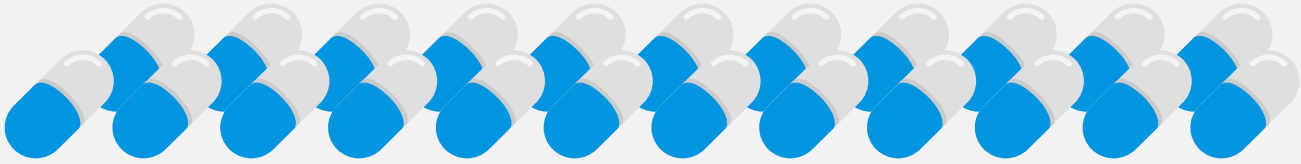
30–60 mcg

A typical multivitamin contains <100 mcg of biotin.

Normal intake of biotin as part of a daily multivitamin poses **no risk of interference**

5000 mcg

Very high doses of biotin are >5,000 mcg per day. This has a potential to lead to test interference.

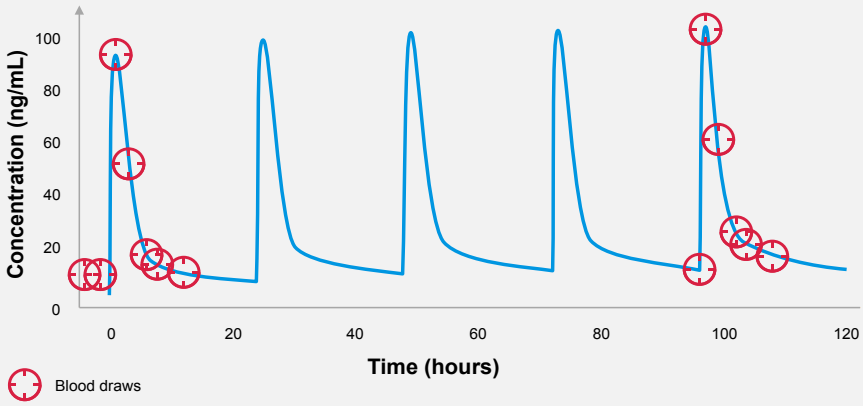


5,000 mcg of biotin = 100 capsules of a typical multivitamin per day

Pharmacokinetic Study

Set-up

Concentration over time



Biotin had linear PK over the range of doses studied (5–20 mg), was rapidly absorbed and had an effective serum half-life of 15 h (steady-state reached in 3 days).

Grimsey et al 2017 *International Journal of Pharmacokinetics*. doi: 10.4155/ipk-2017-0013

Pharmacokinetics study

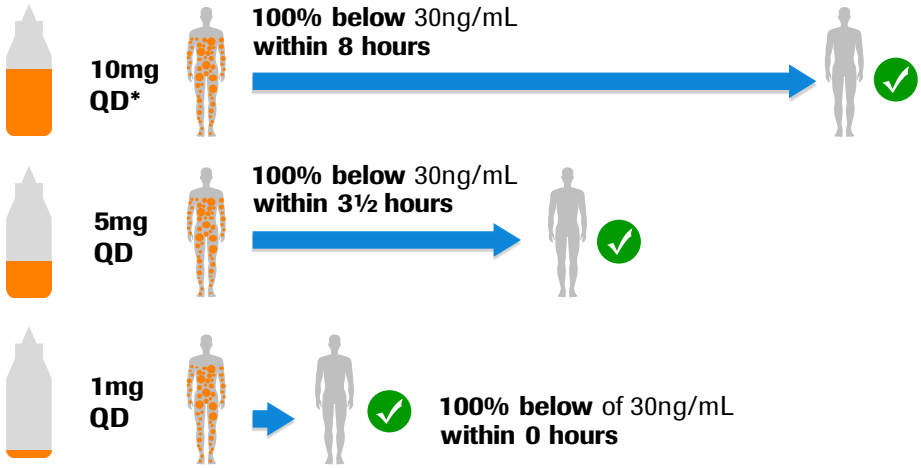
- Healthy volunteers taking biotin N_{subj}=54 (18 per dose group)
- 3 biotin doses (5,000 mcg, 10,000 mcg, or 20,000 mcg per day, 5 days in total)
- Biotin intake for 5 days
- Blood samples taken on days 1, 2, 3, 6, and 7
- Day 3: 1, 3, 6, 8, 12h post biotin intake
  Day 6: 24h post biotin intake
  Day 7: 1, 3, 6, 8, 12h post biotin intake
- Analysis in collaboration with Roche Pharma

Summary

Roche PK Study

Confirmed:

- Pharmacokinetic properties of biotin.
- Plasma levels over time in relation to *in vitro* interference thresholds (used to develop our Package Inserts).



***Doses >10mg:** potential interference in some assays

- For biotin regimens of ≤10 mg QD (10 mg is >300 times the adequate daily intake), serum biotin levels were below the conservative in vitro interference threshold of ≥30 ng/ml after an 8-h washout period.
- In the extreme cases of patients taking a daily dose of >10 mg, longer washout periods are recommended.

We have also re-measured biotin thresholds internally and **confirmed the tolerance thresholds listed in the current Package Inserts.**

Several assays were confirmed to have even more robust tolerance than our current Package Insert claims.

We encourage our lab partners and clinicians to continue to utilize our assays according to the Package Inserts.

In patients receiving therapy with high biotin doses (i.e. **>**5 mg/day), no sample should be taken until **at least** 8 hours after the last biotin administration.

The assay is **unaffected** by icterus (bilirubin <428 µmol/L or <25 mg/dL), hemolysis (Hb <0.621 mmol/L or <1.0 g/dL), lipemia (Intralipid <1500 mg/dL), and **biotin** <123 nmol/L or **<30 ng/mL.***

*Example only - data may vary from assay to assay

Roche is committed to ensuring reliable patient results across all of our Elecsys and cobas h 232 assays. Our thoughtful assay design utilizing biotin helps us deliver consistent, **high quality assays**, with high specificity and lot-to-lot consistency.