

K120504 LIQUICHEK URINE TOXICOLOGY CONTROL, S10 & S10 MINIPAK, LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S20 & LEVEL S20 MINIPAKMar 27, 2012
35 days to decisionK120504 · Product code: **DIF** · Chemistry
Source: <https://www.510kdatabase.net/k120504/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drug Mixture Control Materials (DIF) |
| Date received | Feb 21, 2012 |
| Decision date | Mar 27, 2012 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bio-Rad Laboratories, Inc. |
| Location | Chaska, MN, US |
| Contact | ELIZABETH PLATT |
| Website | http://www.bio-rad.com |
| 510(k) history | 82 submissions · 82 cleared · 1991-2019 |

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...