

K951495 ACCESS TOXO IGG ASSAY ON THE ACCESS IMMUNOASSAY SYSTEMDec 20, 1995
264 days to decisionK951495 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k951495/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD) |
| Date received | Mar 31, 1995 |
| Decision date | Dec 20, 1995 |
| Days to decision | 264 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bio-Rad Laboratories, Inc. |
| Location | Chaska, MN, US |
| Contact | CAROLE STAMP |
| 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...

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