

K852286 DIRRECT AGGLUTINATION(DAG) PREGNANCY TESTJul 9, 1985
41 days to decisionK852286 · Product code: **JHJ** · Chemistry
Source: <https://www.510kdatabase.net/k852286/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agglutination Method, Human Chorionic Gonadotropin (JHJ) |
| Date received | May 29, 1985 |
| Decision date | Jul 9, 1985 |
| Days to decision | 41 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sero-Immuno Diagnostics, Inc. |
| Location | Walker, MI, US |
| Contact | IRVING G KAGAN |
| 510(k) history | 3 submissions · 3 cleared · 1984-1985 |

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