

HysLawScreening_LB001.sas: Hy's Law Screening Validation Program
Use Actual Treatment, Upper Limit of Normal, Last recorded pre-dose measurement
AT Test Elevation and Possible Hy's Law Cases

| Elevated AT Tests | Possible Hy's Law Case | NIC 15 | Placebo |
|----------------------------------|---|---------------|----------------|
| Yes | Yes | 8 (1.8%) | 8 (1.8%) |
| | No | 125 (28.9%) | 104 (23.3%) |
| | | | |
| No | No | 300 (69.3%) | 334 (74.9%) |
| | | | |

HysLawScreening_LB001.sas: Hy's Law Screening Validation Program
Use Actual Treatment, Upper Limit of Normal, Last recorded pre-dose measurement
Counts and Percents Tables

| Lab Test | Test Elevation | NIC 15 | Placebo |
|----------|---------------------|--------------|--------------|
| ALP | Less than 2x | 404 (93.3%) | 405 (90.8%) |
| | Between 2x and 5x | 24 (5.5%) | 33 (7.4%) |
| | Between 5x and 10x | | 3 (0.7%) |
| | Missing Test Result | 5 (1.2%) | 5 (1.1%) |
| | | | |
| ALT | Less than 2x | 196 (45.3%) | 229 (51.3%) |
| | Between 2x and 5x | 122 (28.2%) | 107 (24.0%) |
| | Between 5x and 10x | 45 (10.4%) | 39 (8.7%) |
| | Between 10x and 20x | 9 (2.1%) | 4 (0.9%) |
| | Greater than 20x | 3 (0.7%) | |
| | Missing Test Result | 58 (13.4%) | 67 (15.0%) |
| | | | |
| AST | Less than 2x | 308 (71.1%) | 328 (73.5%) |
| | Between 2x and 5x | 105 (24.2%) | 95 (21.3%) |
| | Between 5x and 10x | 13 (3.0%) | 15 (3.4%) |
| | Between 10x and 20x | 1 (0.2%) | |
| | Greater than 20x | 2 (0.5%) | 1 (0.2%) |
| | Missing Test Result | 4 (0.9%) | 7 (1.6%) |
| | | | |
| BILI | Less than 2x | 403 (93.1%) | 415 (93.0%) |
| | Between 2x and 5x | 21 (4.8%) | 26 (5.8%) |
| | Between 5x and 10x | 4 (0.9%) | 2 (0.4%) |
| | Between 10x and 20x | 2 (0.5%) | 1 (0.2%) |
| | Missing Test Result | 3 (0.7%) | 2 (0.4%) |
| | | | |

HysLawScreening_LB001.sas: Hy's Law Screening Validation Program
Use Actual Treatment, Upper Limit of Normal, Last recorded pre-dose measurement
Counts of Subjects Missing Liver Lab Records

| Lab Test | NIC 15 | Placebo |
|----------|--------|---------|
| ALP | 19 | 14 |
| ALT | 72 | 76 |
| AST | 18 | 16 |
| BILI | 17 | 11 |

HysLawScreening_LB001.sas: Hy's Law Screening Validation Program
Use Actual Treatment, Upper Limit of Normal, Last recorded pre-dose measurement
Counts of Subjects Missing All Tests

| NIC 15 | Placebo |
|-----------|---------|
| 14 | 9 |