

ELANCO'S FEED ASSAY SERVICE



FULL VALUE BEEF™



FEEDASSAY



Through our Full Value Beef partnership, Elanco can help you get the most out of your feed assays by:

- Identifying sampling procedures that match the purpose for the feed assay
- Providing containers, collecting samples and incurring assay costs
- Translating results into improved feeding-management practices



Understanding the Elanco Feed Assay Service

Animal feed additives and medications are thoroughly tested to determine the most effective dosage amount or dosage range. Dosage amounts and ranges also must adhere to regulations established by the U.S. Food and Drug Administration (FDA). The testing and regulations are designed to ensure human health, animal health and optimal results for beef producers.

To ensure optimal animal health, feeds must be correctly delivered to facilities and consistently contain the available nutrients required by animals for body maintenance, growth or reproduction. Several factors in the formulation and manufacturing processes can affect the quality and consistency of feed – factors including bin and equipment cleaning, storage conditions, mixing and pelleting.

To help ensure optimal animal health results through consistent feed, Elanco provides feed assay services for beef producers and feed mill operators. For more information about the feed assay service, contact your Elanco representative.

Feed types

Type A: Medicated articles intended solely for use in the manufacture of another Type A medicated article or in the manufacture of a Type B or Type C medicated feed.

Type B: A medicated feed that contains a Type A medicated article or another Type B medicated feed plus a substantial quantity of nutrients (not less than 25% of the total weight) and is intended solely for use in the manufacturing of another Type B medicated feed or a Type C medicated feed. Before being fed to animals, it has to be substantially diluted with one or more nutrients to produce a Type C medicated feed.

Type C: A medicated feed intended as the complete feed for the animal. Also may be fed “top dressed” (added on top of a usual ration) or offered “free choice” in conjunction with other animal feed. It is manufactured by diluting a Type A medicated article, a Type B medicated feed, or another Type C medicated feed.

Feed categories

- **Category I:** No withdrawal phase
- **Category II:** Product has a withdrawal phase

Assay variance & assay limits

Acceptable assay limits for each product are set by the FDA. The permissible assay variance (also known as the PAV) refers to the limit at which an assay passes or fails. It is based upon the “expected result” of each assay and the “actual result” of each assay.

About feed assays

- Feed assays are laboratory tests that quantify the amount of a specified material contained within a sample of feed
- The feed assay service is a value-added service provided by Elanco to support the proper and optimal use of our products



Understanding Assay Requirements

When to seek a feed assay

Elanco provides feed assays:

- To assess compliance of a Type B or Type C medicated feed from a Category II, Type A medicated article
- As part of a product demonstration evaluation (the Elanco representative will either collect samples or send a representative who is properly trained for sample collection and submission)
- To ensure correct concentration of products due to ration changes or product clearances
- To address product complaints or adverse drug events (ADEs)

When assays are required

- The FDA requires three assays annually for those feed mills holding a medicated feed mill license (any Category II medicated feed)
- When using Elanco products with a zero-day withdrawal in combination with another Category II medicated article, the FDA requires three assays total, to be run annually (rotate assays between each product being used within the combination)

Requirements for submitting a sample

1. Proper container and label

Samples must be in an original Elanco assay bag or bottle with an original customer ID label attached. Assay supplies may be obtained from Elanco sales representatives.

2. Appropriate product box checked

Check the appropriate product box for the sample that you are submitting. Check only one box. If more than one box is checked, the sample will not be assayed.

3. Expected level

Samples without the expected level — expressed in g/ton on an as-is basis — will not be assayed unless prior arrangements have been made. HeifermaX[®] samples may be expressed as mg/lb. If the expected level is unknown, please contact an Elanco sales representative so appropriate measures can be taken.

4. Retesting

There will be no retesting of samples.

5. Shipping

Elanco provides pre-paid UPS shipping labels and cardboard boxes for shipping assay samples. Place the sample in the appropriate shipping container with the proper pre-paid UPS label attached.

Various labels are provided according to the product being shipped:

- a. Dry supplement samples (Rumensin[®], Tylan[®] or Optaflexx[®]) — use UPS 2nd-day air labels
- b. Liquid feed supplement samples (Rumensin, Tylan, Optaflexx or HeifermaX) — use UPS 2nd-day air labels
- c. Rumensin bunk samples — use UPS 2nd-day air labels
- d. Optaflexx bunk samples — use UPS next-day air labels (Optaflexx bunk samples must be shipped UPS next-day air early in the week)

Ship to: Covance Labs • Elanco Assays — Bldg. 418 •
671 S. Meridian Rd. • Greenfield, IN 46140-8501

Proper sampling techniques

1. Obtain samples immediately after feed delivery and prior to cattle having access to the bunk.
2. Use a standardized measuring device or scoop to help ensure consistency of the sample.
3. For routine assays from bunk or supplement samples, obtain a single composite sample from several locations in the bunk or bin.
4. For mixer studies, take three to five uniformly spaced samples from each load of feed.



What is an adverse drug event?

Any observation in animals, whether or not considered product-related, that is unfavorable and unintended, and that occurs after any use of a Veterinary Medicinal Product (VMP) (off-label and on-label uses) is considered to be an ADE. Included are events related to a suspected lack of expected efficacy or noxious reaction in humans after exposure to VMPs. This term may also apply to violations of approved residue limits of an animal drug product in animals or animal products, and/or violations of environmental limits or restrictions associated with exposure to an animal drug product.

Interpreting Results

Results will be reported as g/ton on an as-is basis. The “Acceptable Limits” refer to the “Assay Limits” for the product being assayed and are set by the FDA. Anything within these limits is statistically considered to be 100 percent and, therefore, passes the FDA specifications. The “Percent of Claim” refers to the ratio of the “Actual Result” to the “Expected Level” expressed on a percent basis. An example of a typical assay result is provided below.

Product: **Rumensin for cattle**

Expected Level: **452 g/ton**

Actual Result: **396.6 g/ton**

Acceptable Limits: **85.0 – 115.0 (% of claim)**

Percent of Claim: **87.7%**

STATUS: **PASS**

Contact us

For additional assay bags, bottles, labels and UPS shipping materials, contact your Elanco sales representative. Or, in emergency situations, contact Elanco Animal Health at 1-800-428-4441.

For Rumensin: Consumption by unapproved species or feeding undiluted may be toxic or fatal. Do not feed to veal calves.

For all products: The label contains complete use information, including cautions and warnings. Always read, understand and follow the label and use directions.

Product labels vary by country.

Rumensin: Cattle fed in confinement for slaughter

For improved feed efficiency: Feed 5 to 40 g/ton of monensin (90% DM basis) continuously in a complete feed to provide 50 to 480 mg/hd/d.

For the prevention and control of coccidiosis: Feed 10 to 40 g/ton of monensin (90% DM basis) continuously to provide 0.14 to 0.42 mg/lb of body weight/d of monensin up to a maximum of 480 mg/hd/d.

Rumensin: Growing cattle on pasture or in drylot (stockers, feeders, and dairy and beef replacement heifers)

For increased rate of weight gain: Feed 50 to 200 mg/hd/d of monensin in at least 1.0 lb of Type C medicated feed. Or, after the 5th day, feed 400 mg/hd/d every other day in at least 2.0 lbs of Type C medicated feed. The Type C medicated feed must contain 15 to 400 g/ton of monensin (90% DM basis).

For the prevention and control of coccidiosis: Feed at a rate to provide 0.14 to 0.42 mg/lb of body weight/d of monensin up to a maximum of 200 mg/hd/d. The Type C medicated feed must contain 15 to 400 g/ton of monensin (90% DM basis).

Free-choice supplements: Approved supplements must provide not less than 50 nor more than 200 mg/hd/d of monensin.

Rumensin: Mature reproducing beef cows

For improved feed efficiency when receiving supplemental feed: Feed continuously at a rate of 50 to 200 mg/hd/d of monensin. Cows on pasture or in drylot must receive a minimum of 1.0 lb of Type C medicated feed/hd/d. Do not self-feed.

For the prevention and control of coccidiosis: Feed at a rate of 0.14 to 0.42 mg/lb of body weight/d of monensin up to a maximum of 200 mg/hd/d.

Rumensin: Calves (excluding veal calves)

For the prevention and control of coccidiosis: Feed at a rate of 0.14 to 1.0 mg/lb of body weight/d of monensin up to a maximum of 200 mg/hd/d. The Type C medicated feed must contain 10 to 200 g/ton of monensin (90% DM basis).

Tylan

For the reduction of incidence of liver abscesses: Feed continuously at 8 to 10 g/ton of tylosin (90% DM basis) to provide 60 to 90 mg/hd/d.

Optaflexx: Complete feed

For increased rate of weight gain and improved feed efficiency: Feed 8.2 to 24.6 g/ton of ractopamine hydrochloride (90% DM basis) continuously in a complete feed to provide 70 to 430 mg/hd/d for the last 28 to 42 days on feed.

For increased rate of weight gain, improved feed efficiency and increased carcass leanness: Feed 9.8 to 24.6 g/ton of ractopamine hydrochloride (90% DM basis) continuously in a complete feed to provide 90 to 430 mg/hd/d for the last 28 to 42 days on feed.

Optaflexx: Top dress

For increased rate of weight gain and improved feed efficiency: Feed 70 to 400 mg/hd/d of ractopamine hydrochloride (90% DM basis) continuously in a minimum of 1.0 lb/hd/d top dress Type C medicated feed (maximum 800 g/ton ractopamine hydrochloride) during the last 28 to 42 days on feed.

HeifermaX: Heifers fed in confinement for slaughter

For increased rate of weight gain, improved feed efficiency and suppression of estrus (heat):

Feed 0.5 to 2.0 lb/hd/d of melengestrol acetate in a Type C medicated feed to provide 0.25 to 0.5 mg/hd/d.

HeifermaX: Heifers intended for breeding

For suppression of estrus (heat): Thoroughly mix HeifermaX in the supplement to provide 0.5 mg/hd/d of melengestrol acetate.

Rumensin® is a trademark for Elanco's brand of monensin sodium.

Tylan® is a trademark for Elanco's brand of tylosin.

Optaflexx® is a trademark for Elanco's brand of ractopamine hydrochloride.

HeifermaX® is a trademark for Elanco's brand of melengestrol acetate.

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FEEDASSAY

