

Section 1 – Product and Company Identification

1.1 Manufacturer Information

Quidel Corporation	Phone:	1.800.874.1517	Web:	quidel.com
2005 East State Street, Suite 100	Fax:	1.740.592.9820	E-mail:	gehs@quidel.com
Athens, OH 45701	Emergency (24-Hour):	1.866.519.4752		

1.2 Product Information

Product Name: PYD/DPD HPLC Calibrator (Catalog #: 8004)

Intended Use: The PYD/DPD Calibrator is designed for the calibration of HPLC equipment used in the determination of pyridinoline (PYD) and deoxypyridinoline (DPD) concentration in urine samples. For Research Use Only.

Components: PYD/DPD Calibrator (750 µL)

Section 2 – Hazard Identification

- 2.1 Classification of the Substance of Mixture** Not a hazardous substance or mixture.
- 2.2 GHS Label Elements, including Precautionary Statements** Not a hazardous substance or mixture.
- 2.3 Supplemental Hazard Statements**
- Contains potentially infectious materials. Refer to Universal Precautions information in Section 7, Handling and Storage.

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Chemical Name	CAS #	EINECS #	Concentration (%)	Component Volume
Acetic Acid	64-19-7	200-580-7	1.2	750 µL

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

If inhaled: Move the person to fresh air and support breathing as required.

In case of skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

In case of eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

Section 5 – Fire Fighting Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

5.1 Suitable Extinguishing Media

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

Section 5 – Fire Fighting Measures (cont'd)**5.2 Special Hazards Arising from the Substance or Mixture**

Nature of decomposition products not known.

5.3 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.4 Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of any of the components listed in this SDS is unlikely.

6.1 Personal Precautions

Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the Bone Health antibodies or proteins. Avoid breathing vapors, mist or gas. Keep all unnecessary personnel away from the spill area.

6.2 Methods and Materials for Clean-Up

Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.

6.3 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

6.4 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

Section 7 – Handling and Storage**7.1 Specific Use**

For professional use only – Not for use by the general public.

7.2 Precautions for Safe Handling

As with all chemical and biological substances, avoid getting these components ON YOU or IN YOU. Wash exposed areas thoroughly after using these components. Do not eat or drink while using these components. These components should be handled only by qualified clinical or laboratory employees trained on the use of these antibodies and proteins and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with these components. Keep out of reach of the general public.

7.3 Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

7.4 Conditions for Safe Storage (including any incompatibilities)

To maintain efficacy, store according to the Package Insert instructions.

7.5 Incompatibilities

To maintain efficacy, store according to the Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection**8.1 Exposure Limits**

No data available for the Bone Health Antibodies and Proteins.

8.2 Exposure Controls

Engineering Measures

Use with adequate ventilation.

Section 8 – Exposure Controls and Personal Protection (cont'd)
Personal Protective Equipment
Respiratory Protection

None needed under normal conditions of use.

Skin Protection

Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling these components.

Eye Protection

Wear safety glasses with side shields or goggles to prevent eye contact.

Body Protection

Use body protection appropriate for the task. A laboratory coat is recommended.

Hygiene Measures

Wash hands before use, after use and at the end of the workday.

8.3 Environmental Exposure Controls

No special environmental controls are required.

8.4 Special Notes

No data available.

Section 9 – Physical and Chemical Properties

Characteristic	PYD/DPD HPLC Calibrator
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	2.4
Solubility in Water	Soluble
Appearance and Odor	Liquid, clear with vinegar like odor

Section 10 – Stability and Reactivity

Characteristic	PYD/DPD HPLC Calibrator
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

Section 11 – Toxicological Properties
11.1 Information on Toxicological Effects

Acute Toxicity

Chemical Name	CAS #	RTECS #	Information
Acetic Acid	64-19-7	AF1225000	Inhalation LC50 Rat 11.4 mg/L 4h
			Oral LD50 Rat 3310 mg/kg
			Dermal LD50 Rabbit 1112 mg/kg

Skin Corrosion / Irritation No data available

Respiratory or Skin Sensitization No data available

Generative Cell Mutagenicity No data available

Carcinogenicity No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.

Reproductive Toxicity No data available

Teratogenicity No data available

Specified Target Organ Toxicity

Single Exposure: No data available Repeated Exposure: No data available

Aspiration Hazard No data available

Potential Health Effects

Inhalation: May cause respiratory tract irritation.

Skin: May cause skin irritation upon contact.

Ingestion: May be harmful if swallowed.

Eyes: May cause eye irritation.

11.2 Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

11.3 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

Section 12 – Ecological Information
12.1 Toxicity No data available

12.2 Persistence and Degradability No data available

12.3 Bioaccumulative Potential No data available

12.4 Mobility in Soil No data available

12.5 PBT and vPvB Assessment No data available

12.6 Other Adverse Effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

Section 13 – Disposal Considerations

13.1 Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the control stocks into drains, water courses or onto the ground.

13.2 Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

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|---|---|
| 14.1 U.S Department of Transportation (DOT) | These components are not regulated for transport. |
| 14.2 International Air Transportation Association (IATA) | These components are not regulated for transport. |
| 14.3 International Maritime Dangerous Goods (IMDG) | These components are not regulated for transport. |

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

- | | |
|---------------------|---|
| OSHA Hazards | None |
| SARA 302 | The following chemicals are subject to reporting levels established by Sara Title III, Section 302:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302. |
| SARA 313 | The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313. |
| SARA311/312 Hazards | Acetic Acid CAS#: 64-19-7 Fire Hazard, Acute Health Hazard, Chronic Health Hazard |

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Acetic Acid	64-19-7	Yes	Yes	Yes	Yes	Yes	Yes

California Prop 65: This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
Acetic Acid	64-19-7	--

15.4 Additional Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Mixture No data available

Chemical Safety Assessment Not completed for the components contained within this kit.

HMIS Kit Classification:

Health Hazard: 1
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard: 0

NFPA Kit Classification:

Health Hazard (blue): 1
 Fire Hazard (red): 0
 Reactivity (yellow): 0
 Special Hazards (white): None

* Use additional care when handling the PYD/DPD HPLC Calibrator samples as they contain materials from animal or human origin.

Section 16 – Other Information

PREPARED BY: Quidel Corporation
12544 High Bluff Drive, Suite 200
San Diego, CA 92130

SUPERSEDES: --

REVISIONS: New

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event, shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.